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IN THE
Supreme Court of the United States
OCTOBER TERM, 1995

SOFAMOR DANEK GROUP, INC.,
Petitioner,

v.

CLIFTON R. GAUS, *et al.*,
Respondents.

Petition for a Writ of Certiorari to the United States Court of Appeals for the District of Columbia Circuit

PETITION FOR A WRIT OF CERTIORARI

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QUESTIONS PRESENTED

The Department of Health and Human Services (HHS), through the Agency for Health Care Policy and Research (AHCPR) and a panel of experts known as the Expert Panel on Low Back Problems (Low Back Panel), after meeting in secret for two years and after spending more than $1 million in public funds, has developed what is called a Clinical Practice Guideline (CPG) on Low Back Pain. Published and disseminated with the official sanction of the government, this CPG addresses the medical treatment of low back problems. With the government's imprimatur, federal officials are using the Low Back CPG in the administration of the Medicare and Medicaid programs, while public and private health care professionals also use this CPG to guide their treatment decisions. The questions presented are the following:

1. Whether Congress or the Executive must expressly identify the federal government as an intended beneficiary of the work product of a group of private experts "established" to generate "advice or recommendations" within the meaning of the Federal Advisory Committee Act (FACA), 5 U.S.C. app. 2 § 1, in order for that group to be subject to FACA.

2. Whether Congress or the Executive must expressly announce its intent to "utilize" a group of private experts for their "advice or recommendations" within the meaning of FACA before in fact utilizing their work product in order for that group to be subject to FACA.

3. Whether the Expert Panel on Low Back Problems was "established" or "utilized" by the government "in the interest of obtaining advice or recommendations," and therefore is an "advisory committee" for purposes of FACA.

PARTIES TO THE PROCEEDING

Petitioner Sofamor Danek Group, Inc., is a publicly held corporation. None of its subsidiaries or affiliates has issued shares or debt security to the public. Appellees in the court of appeals and defendants in the district court were J. Jarrett Clinton, the then-Administrator for the Agency for Health Care Policy and Research; Philip R. Lee, Assistant Secretary for Health, Public Health Service; Donna Shalala, Secretary of Health and Human Services; the Agency for Health Care Policy and Research; and the United States of America. The individual defendants were sued in their official capacities. Pursuant to Fed. R. App. P. 43(c), Clifton R. Gaus, who is now the Administrator of the Agency for Health Care Policy and Research, later was substituted as a party.

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PETITION FOR A WRIT OF CERTIORARI

Sofamor Danek Group, Inc., petitions for a writ of certiorari to review the judgment of the United States Court of Appeals for the District of Columbia Circuit in this case.

OPINIONS BELOW

The opinion of the court of appeals, App. 1a-16a, is reported at 61 F.3d 929. The opinion of the district court, App. 17a-31a, is not officially reported.

JURISDICTION

The judgment of the court of appeals was entered on August 4, 1995. App. 33a-34a. The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

STATUTES INVOLVED

Pertinent statutes are reproduced in the appendix to this brief.

STATEMENT

I. The Statutory Background

A. *The Agency For Health Care Policy And Research And Clinical Practice Guidelines*

Congress created the Agency for Health Care Policy and Research (AHCPR) in the Omnibus Budget Reconciliation Act of 1989 [1] in order to improve the quality, appropriateness, and effectiveness of health care in this country. 42 U.S.C. § 299b-1(a). To do so, Congress ordered AHCPR to see to development of Clinical Practice Guidelines (CPGs), parameters for diagnosing, treating, managing, and preventing selected medical conditions. *Id.* § 299b-1(a). Congress required that CPGs be based on a comprehensive review of the best available scientific research and professional judgment and that they be presented in formats appropriate for use by physicians, health care practitioners and providers, medical educators, and medical review organizations. *Id.* § 299b-1(b). In the OBRA, Congress also established the Forum for Quality and Effectiveness in Health Care (Forum), the body within AHCPR directly responsible for overseeing development of CPGs. *Id.* § 299b. Both AHCPR and the Forum are funded by the federal government.

Through the OBRA, Congress instructed AHCPR to develop CPGs by convening panels of medical experts and consumers that would generate CPGs for specific medical conditions considered important by AHCPR. 42 U.S.C. § 299(b)-2. Congress also instructed AHCPR to contract with public and nonprofit private entities to gather

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[1] *See* the Omnibus Budget Reconciliation Act of 1989, Pub. L. No. 101-239, § 901, 103 Stat. 2189 (1989) (OBRA), which amended the Public Health Service Act, 42 U.S.C. §§ 201-300aaa (West 1991 & Supp. 1993), and the Social Security Act, 42 U.S.C. §§ 1301-1395ccc (West 1992 & Supp. 1993). *See also* AHCPR Reauthorization Act of 1992, Pub. L. No. 102-410, 106 Stat. 2094 (1992) (reauthorizing AHCPR and amending OBRA).

information regarding medical conditions addressed in CPGs and to update them as necessary. *Id.* § 299b-2(a). The OBRA set rules for the establishment and operation of CPG panels, and also defined their purpose: to develop and review guidelines, inter alia, to "*provid*[*e*] *advice to the Administrator* [*of the AHCPR*] *and the Director* [*of the Forum*]." *Id.* (emphasis added). Congress fixed stringent standards for convening panels, selecting panel members, and setting the agenda for guideline topics. *Id.* §§ 299b-2, 299b-3.

B. *The Federal Advisory Committee Act*

The Federal Advisory Committee Act (FACA), 5 U.S.C. app. 2 § 1, regulates the government's use of "advisory committees": *viz.*, groups of private experts "established" or "utilized" by the Executive Branch "in the interest of obtaining advice or recommendations." 5 U.S.C. app. 2 § 3(2). Congress adopted FACA so that the public could oversee the work of advisory committees to ensure that tax dollars are spent wisely on and by such committees and to avoid the risk that potentially biased individuals do not exercise undue influence over government officials. *Public Citizen v. Department of Justice*, 491 U.S. 440, 453 (1989). FACA imposes a number of obligations on advisory committees and on the government agency to which they report. For example, advisory committee meetings must be open to the public (subject to exemptions in the Government in the Sunshine Act, 5 U.S.C. 552b), and interested persons must be permitted to attend and appear before (or to file statements with) the advisory committee. 5 U.S.C. app. 2 § 10(a) and (d). Advisory committees must keep detailed minutes of their meetings, and (subject to exemptions in the Freedom of Information Act (FOIA), 5 U.S.C. § 552) they must make available for public inspection and copying all agendas, minutes, and transcripts of their meetings, as well as all records prepared by or made available to them. *Id.* § 10(b) and (c). Any federal agency to which such

a committee renders advice must provide the public with the same access to those documents. *Id.*

II. The Proceedings Below

The government consistently has refused to require Expert Panels to adhere to FACA, and it has permitted only very limited public involvement in the Panels' work.[2] The Low Back Panel has followed that settled procedure of limiting public access severely.[3] In fact, "[i]t is undis-

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[2] Just as the government kept secret the work of the panel developing health care policy headed by Hillary Rodham Clinton, *Association of Am. Physicians & Surgeons v. Clinton*, 997 F.2d 898 (D.C. Cir. 1993), so, to, did AHCPR choose to restrict severely public access to Expert Panels. When AHCPR convenes a new guideline panel, it publishes a notice in the *Federal Register* seeking nominations for panel members and chairpersons. After AHCPR appoints the members, the panel holds a series of closed meetings to define the goals and scope of the project and the scientific evidence to be considered. *AHCPR Fact Sheet* 2 (Jan. 1992); C.A. App. 97. The panel members thereafter address, and prepare a written report on, various health policy issues, such as costs, medical liability, use of limited resources, and concerns of patients, practitioners, and payers that may affect the implementation of the guideline. U.S. Department of Health and Human Services, *AHCPR Interim Manual for Clinical Practice Guideline Development*; C.A. App. 19. After generating its report, each panel holds one open forum to allow interested parties to present oral or written testimony to panel members on the specific health issues addressed by the panel. *Id.* Each panel next prepares a draft CPG, which is distributed to outside experts for peer review without opportunity for public participation or comment. *Policy & Procedure Manual for Guideline Panel Chairs* 3-12 to 3-13 (Apr. 1993); C.A. App. 137. Each CPG is then finalized, published, and distributed.

[3] On March 18, 1991, AHCPR announced in the *Federal Register* its intent to convene a panel to develop a CPG for lower back disorders, and invited nominations for panel members. 56 Fed. Reg. 11,452 (1991). The only other opportunity offered by AHCPR for public involvement in the work of the Low Back Panel was a public meeting held on September 16, 1992, that was little more than a formality. The meeting lasted only two hours and ten minutes; it was held more than two and one-half years before the publication of the CPG; public participants were limited to five-minute

puted that the Low Back Panel did not comply with FACA's public access requirements." App. 5a n.17. Petitioner, through its subsidiaries, develops, manufactures, and distributes medical devices, including instruments for use by surgeons in spinal fusion surgery to treat spinal disorders. Petitioner made every effort informally to persuade the government to bring the Low Back Panel into compliance with FACA, but its efforts were unsuccessful.[4]

A. *The Proceedings In District Court*

Petitioner filed a complaint seeking declaratory and injunctive relief, on the ground that the government had violated FACA in the course of developing the Low Back CPG. After limited discovery, the district court granted summary judgment for the government, ruling that the Low Back Panel was not an "advisory committee" under FACA. App. 17a-31a.

At the outset, the district court concluded that the Low Back Panel was established by AHCPR, not by statute, and thus was not an advisory committee under FACA § 3(2)(A), *viz.*, a panel established by statute in the interest of obtaining advice for federal officials. App. 24a. The court acknowledged that "several federal agencies, such as the Health Care Finance Administration (HCFA)

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presentations; and the Principal Investigator of the research team for the Panel (*i.e.*, the Patient Outcome Research Team or PORT) did not attend the forum. 57 Fed. Reg. 32,991 (1992); Open Forum Tr. 8, 11; C.A. App. 105. Petitioner determined it could not reasonably address the various, complicated issues involved in the treatment of back disorders and spinal surgery in a five-minute presentation and chose not to send a representative to the meeting.

[4] Petitioner requested that AHCPR open the Low Back Panel to the public in accordance with FACA. AHCPR responded that, in its view, FACA does not apply to Expert Panels, since they are not advisory committees. Petitioner reiterated its request in correspondence to, and in meetings with HHS officials. Nonetheless, HHS ultimately informed petitioner that it refused to require the Low Back Panel to comply with FACA. C.A. App. 205, 220-226.

—an agency within the Department of Health and Human Services that oversees federal spending under the Medicare and Medicaid programs—would potentially utilize the CPG." App. 26a. Nonetheless, the court deemed that fact irrelevant, since Congress empowered AHCPR to establish Expert Panels to advise physicians on appropriate medical treatments. Any use of CPGs by HCFA or other government agencies, the district court said, was "optional" and immaterial. App. 26a-27a. Accordingly, the court held, AHCPR did not establish the Low Back Panel "in the interest of obtaining advice or recommendations" and thus did not meet FACA § 3(2)(C)'s definition of advisory committee.[5]

B. *The Proceedings In The Court Of Appeals*

The court of appeals affirmed. App. 1a-16a. Starting from the premise that "the Low Back Panel was established by the federal government within the meaning of FACA," *id.* at 6a, the court said that "the dispositive issue as to establishment is whether the Panel's purpose was to provide 'advice or recommendations' to HCFA or other federal entities," *id.* The court concluded that the Low Back Panel had not been established for that purpose "[i]n light of Congress' stated purpose for the clinical practice guidelines and the absence of evidence of additional, unstated purposes," *id.* For that reason, the court held, the Low Back Panel was not an advisory committee under FACA § 3(2)(A). App. 6a. In addition, the court said that it found "no convincing evidence that HCFA or any other agency 'utlized' the Low Back panel to obtain 'advice or recommendations,'" and thus held that the Panel was not an advisory committee under FACA § 3(2)(C). App. 6a-7a. The court reached that conclusion because it said that there was no record evidence proving that, "*at the time* the Low Back Panel was appointed," the government intended to use its CPG to formulate health care policy. App. 13a (emphasis added).

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[5] The government thereafter published the CPG.

The court so ruled despite its recognition, *first*, that the Health Care Finance Administration (HCFA), a component of HHS, in fact may use CPG in policymaking decisions and, *second*, that Congress may have intended HCFA to do so. In the court's words:

> Although HCFA may consult the *Clinical Practice Guideline on Acute Low Back Problems in Adults* when setting Medicare reimbursement policy, *and Congress may have intended that HCFA do so*, it does not follow that Congress' purpose in authorizing the panels to develop a clinical practice guideline like the *Guideline on Acute Low Back Problems in Adults* was to provide advice or recommendations to the Secretary or HCFA.

App. 10a-11a (emphasis added; footnotes omitted). The government's reliance on that CPG for such a purpose, the court said, would be only an "optional use" of such advice or only a "secondary effect of Congress's decision that guidelines should be developed for clinical health care practitioners." *Id.* at 13a.

REASONS FOR GRANTING THE PETITION

This case presents important, recurring, and unsettled questions concerning the proper legal analysis for determining whether a group of private experts convened by the government for the purpose of generating recommendations used by government officials and private individuals alike is subject to the requirements of FACA. Each year, health care personnel spend thousands of hours treating various injuries and diseases under different medical regimens, and each year the government spends billions of dollars in the Medicare and Medicaid programs underwriting those treatments. Expert Panels, including the Low Back Panel, have played a prominent role in that process, at considerable public expense, by drafting publications for use by the health care profession in two discrete ways. Medical professionals, within and outside of the federal government, will make individual patient treat-

ment decisions in reliance on Expert Panels' CPGs. Equally important, HHS policymaking officials will rely on those recommendations in making broad-based decisions about the allocation of federal funds for treatment of and research concerning injury and disease. Given the functions performed by these panels, the federal government's reliance on their work product, and their potent effect on the expenditure of federal Medicare funds, Expert Panels are a textbook example of the type of influential private organization that Congress sought to regulate through the broad scope of FACA.

Despite those undisputed facts, the D.C. Circuit held that the Low Back Panel is not subject to the FACA. In so ruling, that court made two fundamental mistakes. *First*, the court held that Expert Panels are not established for the purpose of advising the government, since Congress did not *in terms* declare that *both* the government *and* private parties will use their work product. In so ruling, the court of appeals violated basic principles of statutory construction requiring a court to consider the text of the entire statute, not just one component, as well as the purpose and policies that the statute seeks to advance. *Second*, the court held that the Low Back Panel was not utilized for the purpose of advising the government, since there was no evidence that the panel would be so used when it was established. In so ruling, the court ignored not only overwhelming record evidence proving that the government would rely on this panel's recommendations, but also the text of OBRA, which *in terms* directed AHCPR to develop CPGs of use to HCFA and which (since it created AHCPR) *necessarily* existed before any Expert Panel was launched. The decision below, therefore, clearly misconstrued both FACA and OBRA.

That decision likely will have serious adverse consequences both for application of FACA to Expert Panels and other private bodies, as well as for the efficient development of national health care policy. During the recent

budget process, AHCPR has claimed that CPGs are indispensable to the rational development of the Medicare program due to the advice they convey to private practitioners and government officials alike in choosing sensible cost-efficient treatments for Medicare patients. Unfortunately, however, the government simultaneously has refused either itself intensively to scrutinize the operation of these Expert Panels or to permit the public to undertake such oversight by applying FACA to them. The result is that panels secretly develop recommendations that AHCPR claims are entitled to the same respect that would be accorded to the work of neutral, unbiased, and properly-examined experts. For that reason, in light of their provenance CPGs at best have a tainted pedigree and at worst should be disregarded as the self-interested opinions of possibly biased individuals. Neither diagnosis is a healthy one or is one that Congress foresaw when it enacted OBRA. Accordingly, since most litigation under that law has been brought in the District of Columbia, the decision below warrants review by this Court despite the absence of a square conflict among the circuits on the particular panel at issue here.

I. THE DECISION BELOW IS ERRONEOUS

The text of OBRA and the record below make clear that Expert Panels were established "in the interest of" obtaining the advice that a Panel would develop regarding the medical and policy aspects of treatment decisions.[6] Because that is all that FACA requires before a group must be treated as an "advisory committee," OBRA dictates that the Low Back Panel comply with the FACA's requirements.

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[6] The D.C. Circuit concluded without much discussion that the Low Back Panel was created by AHCPR, rather than by Congress. In our view, the D.C. Circuit was mistaken; Congress established Expert Panels. For present purposes, however, it is unnecessary to resolve that question, since the courts below agreed that the *government* brought Expert Panels into being or will utilize them.

A. OBRA proves that Expert Panels are established, at least in part, "in the interest of obtaining advice or recommendations" for federal officials. Several provisions of OBRA show that Congress wanted AHCPR to develop CPGs in order to benefit federal policymakers. *First*, Congress specifically directed AHCPR to develop "an initial set of guidelines, standards, performance measures, and review criteria * * * that includes not less than 3 clinical treatments or conditions described in [Medicare]," 42 U.S.C. § 299b-1(d) (citing 42 U.S.C. § 1320b-12(a)(3)), *viz.*, "clinical treatments or conditions" that "account for a significant portion of expenditures under subchapter XVIII of [the Social Security Act, *i.e.*, Health Insurance for Aged and Disabled, 42 U.S.C. § 1395]," that "have a significant variation in the frequency of the type of treatment provided," or that "otherwise meet the needs and priorities of [Medicare]." 42 U.S.C. § 1320b-12(a)(3)(A)(i)-(ii). *Second*, "[t]o assure an appropriate reflection of the needs and priorities of the [Medicare] program," Congress added that "activities under this part that affect such program shall be conducted consistent with [Medicare]." 42 U.S.C. § 299b-1(e). *Third*, OBRA directed AHCPR to ensure that guidelines are developed by January 1, 1996, addressing prevention of at least three "conditions that account for significant national health expenditures." 42 U.S.C. § 299b-1(f). *Fourth*, because Congress anticipated that the Forum, the body within AHCPR directly responsible for overseeing development of CPGs, would reflect the views of qualified Medicare health care practitioners, H.R. Rep. No. 247, 101st Cong., 1st Sess. 377-79 (1989), to ensure that AHCPR carries out those duties OBRA requires AHCPR to consult with HCFA in setting an agenda for development of CPGs. 42 U.S.C. § 299b-3(a)(1) and (2)(B).

As Justice Holmes reminded us, "[t]here is no canon against using common sense in construing laws as saying what they obviously mean." *Roschen v. Ward*, 279 U.S.

337, 339 (1929). Here, common sense dictates that Expert Panels were created in part to advise the government about health care treatment options. The first three provisions show that Congress anticipated—indeed, desired—that CPGs would be useful to the Medicare program. The last provision demonstrates that Congress wanted to avoid the risk that AHCPR would misjudge "the needs and priorities of the [Medicare] program," 42 U.S.C. § 299b-1(e), by requiring AHCPR to consult with HCFA about those matters. The text of OBRA therefore demonstrates that the reason why Congress not only directed AHCPR to ensure that health issues of concern to Medicare were fully considered, but also placed those problems at the head of the queue, is that *Congress wanted Expert Panels to draft CPGs that would be of use to HCFA in the administration of Medicare.*[7]

The D.C. Circuit gave no weight to the provisions of OBRA discussed above. According to the court below, because Congress said that CPGs would benefit the medical community and did not also say that they would bene-

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[7] The same point can be made by answering several straightforward questions: Why else did Congress order AHCPR to ensure that CPGs are useful for Medicare? Why else would Congress have taken such pains to ensure that, early in AHCPR's life, Expert Panels addressed medical problems and recommended treatments of concern to Medicare? Why else did Congress direct AHCPR initially to develop three CPGs that help prevent "significant national health expenditures"? Why else did Congress direct AHCPR to work closely with HFCA officials in order to ensure that the work of Expert Panels would be guided by the wishes of Medicare administrators? Why else did Congress take such pains to require coordination between the research arm of this enterprise (AHCPR) and the funding supervisor for Medicare (HCFA) if Congress did not intend that CPGs would supply advice to the officials of the latter? Accordingly, since Congress, like the public, "is presumed to intend the natural and probable consequences" of its own acts, *Allen v. United States*, 164 U.S. 492, 496 (1896), the most reasonable explanation why Congress imposed the foregoing duties on AHCPR and HCFA is that *Congress wanted HCFA to be guided by AHCPR's Expert Panels' recommendations.*

fit the government, Expert Panels were not established, even in part, for the latter purpose. App. 7a & nn.20-21. But that reading of FACA is unduly simplistic. Statutory interpretation is a "holistic endeavor," *United Savings Ass'n of Texas v. Timbers of Inwood Forest Assocs.*, 484 U.S. 365, 371 (1988), and the D.C. Circuit's reading of OBRA does not reflect accurately its dual purpose of advising the medical community *and* government officials. If Congress had wanted only to create for the medical profession guidelines resembling the ALI's *Restatements*, Congress would have funded a grant program so that a university, foundation, or association could draft them. Instead, Congress created a new federal bureaucracy to staff and supervise the drafting of these guidelines since Congress believed that only a new federal agency could undertake the oversight necessary to ensure that the interests of the Medicare program were adequately served.

B. The record below also proves that the government has utilized Expert Panels, however that term is defined, "in the interest of obtaining their advice or recommendations," and will continue to do so.[8]

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[8] FACA independently defines an advisory committee as a panel that is "utilized" by federal officials. 5 U.S.C. app. 2 § 3(2)(C). Neither FACA's text nor its legislative history defines the term "utilized." *See* S. Rep. No. 1098, 92d Cong., 2d Sess. 1, 3-6, 16 (1972); H.R. Rep. No. 1017, 92d Cong., 2d Sess. 6, 8, 10 (1972); H.R. Conf. Rep. No. 1403, 92d Cong., 2d Sess. 2 (1972); *House Comm. on Government Operations, The Role and Effectiveness of Federal Advisory Committees*, H.R. Rep. No. 1731, 91st Cong., 2d Sess. 1-23 (1970). Under these circumstances, the term "utilized" ordinarily would be given its common meaning, *see Asgrow Seed Co. v. Winterboer*, 115 S. Ct. 788, 793 (1995), of "to make use of," *Merriam-Webster's Collegiate Dictionary* 1302 (10th ed. 1993). Nonetheless, in *Public Citizen* a majority of this Court, in a narrow ruling influenced greatly by the need to avoid a potentially unconstitutional interpretation of FACA, held that the Executive did not "utilize" the American Bar Association Standing Committee on Federal Judiciary, even though the government "made use of" the ABA Committee's advice about potential judicial nominees. 491 U.S. at 452-67. By contrast, three members of the Court concluded

1. Officials at HCFA—the agency within HHS responsible for administering Medicare and Medicaid—presently are using published CPGs to develop standards of care and medical review criteria for Medicare populations. For example, Bruce Vladek, HCFA Administrator, testi-

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(correctly, in our view) that the term should be given its ordinary, dictionary meaning. *Id.* at 469-82 (opinion of Kennedy, J., joined by Rehnquist, C.J., & O'Connor, J.). Since then, the D.C. Circuit has narrowly defined the term "utilize," ruling that it applies only when a panel is "organized by a nongovernmental entity but nonetheless [is] so 'closely tied' to an agency as to be amenable to 'strict management by agency officials.'" *Food Chemical News v. Young*, 900 F.2d 328, 333 (D.C. Cir. 1990) (Ginsburg, J.) (citation omitted); *Washington Legal Foundation v. United States Sentencing Comm'n*, 17 F.3d 1446, 1450-51 (D.C. Cir. 1994).

Here, the government clearly will "utilize" the Low Back Panel's advice under any definition of that term. Both OBRA and the record below prove that the government will "make use of" CPGs. For instance, the Department of Labor unambiguously has said that it will use the Low Back CPG for advice in administration of the Federal Employees Compensation Act, 5 U.S.C. § 8101 (FECA). C.A. App. 136 (March 10, 1993, letter of Lawrence W. Rogers, then-Director of the Office of Workers' Compensation Programs, Department of Labor, to Barbara Fleming, M.D., a senior health policy analyst in the AHCPR Forum). Moreover, the record proves that the government's own health care personnel will make use of CPGs in making individual decisions in the health care programs administered by, for example, the Department of Defense, Interior, and Veterans Affairs. In addition, OBRA proves that AHCPR "strictly manages" Expert Panels since OBRA vests in AHCPR complete control over panels: AHCPR has the power to appoint all members and chairs of panels; AHCPR defines the specific conditions to be addressed by each panel; it sets the priorities in which those conditions will be addressed; and it charts the scope and goals of each panel. 42 U.S.C. §§ 299b-2 and b-3. Finally, AHCPR's Administrator has the power to remove the chair and members of each Expert Panel. Deposition of Carole Hudgings, Acting Adm'r AHCPR 46; C.A. App. 276. The power to remove panel members alone is proof that AHCPR exercises "control" over panels. *See Bowsher v. Synar*, 478 U.S. 714, 726-28 (1986) (Congress's power to remove an officer constitutes "control" over that officer); *WLF*, 17 F.3d at 1451 (control is present when panel members "answer to" federal officials).

fied before Congress that "[i]n quality monitoring, HCFA uses clinical practice guidelines (guidelines on appropriate medical practice), including those developed by [AHCPR], as well as the private sector."[9] This effort complements the work of HCFA's Medicare Utilization and Quality Control Professional Review Organization (PRO) and provides strong evidence of a commitment by federal agencies to utilize CPGs for recommendations in developing strategies for diagnosis, treatment, and health care management. 58 Fed. Reg. 12,042 (1993).[10] In so doing, HCFA has acknowledged that one of the most "important forces driv[ing]" this project is the development of "clinical practice guidelines," which "provide potential blueprints for quality improvement efforts in the clinical areas they address." *Id.* HCFA also has acknowledged that it will use CPGs to develop reimbursement policies for Medicare and Medicaid and to train practitioners in those programs.[11]

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[9] HHS, *Statement of Bruce C. Vladeck, Ph. D., Administrator Health Care Financing Administration, Before the Ways and Means Subcommittee on Health* 2 (Mar. 21, 1995) (hereinafter *Vladek Statement*); *see also id.* at 6.

[10] HCFA explained the purpose of the PRO as follows: "The PRO program was enacted to ensure that services provided to Medicare beneficiaries and reimbursed through title XVIII are: (a) Reasonable and medically necessary and otherwise not in violation of section 1862 of the Social Security Act; (b) Of a quality which meets professionally recognized standards of health care; and (c) Provided in the most effective and economic setting." 58 Fed. Reg. at 12,043.

[11] In a cover letter sent to Medicare and Medicaid health providers with enclosed sets of CPGs, HCFA officials discussed the value of the CPGs: "We believe [the CPGs] are important support documents to the Health Care Financing Administration's (HCFA) continuing responsibilities to promote quality of care for Medicare and Medicaid beneficiaries. * * * * * HCFA will also use these guidelines in training State agency and regional office health facility surveyors. * * * * * We believe you will find the information in these guidelines as beneficial as we have in our continuing efforts to help meet "state-of-the-art" informational needs of Medicare

Other HHS officials also have acknowledged that HCFA will "utilize" CPGs for the purpose of gleaning advice about the formulation of national health care policy. Philip Lee, HHS Assistant Secretary of Health, told Congress that "the needs and priorities of the Medicare program are reflected in AHCPR-supported guidelines and other research activities," and also that "[s]upport under this authorization comes from both Medicare trust funds and appropriated money." [12] Thomas Hoyer, Acting Director of the Office of Coverage and Eligibility Policy, Bureau of Policy Development of HCFA, said that HCFA refers (inter alia) to CPGs in setting reimbursement policies. C.A. App. 272. Beverly Dennis, III, HHS Deputy General Counsel, conceded that federal officials will use CPGs to improve quality and conserve costs of services under Medicare and Medicaid. C.A. App. 226.[13] AHCPR has said that Congress created the CPG program because of its "concern that health dollars spent by patients or their families, insurers, employers, and *Federal and State programs such as Medicare and Medicaid* are being wasted on ineffective or inappropriate care." *AHCPR Fact Sheet* 1 (Jan. 1992) (emphasis added); C.A. App. 97. And AHCPR has said that "[c]ollaborative efforts will continue with [HCFA], other components of the Public Health Service (PHS), such as the National Institutes of Health (NIH), [the Health Resources and Services Administration], and the Indian Health Service,

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and Medicaid providers." Letter from William Toby, Jr., and James O. Mason, M.D. (Jan. 5, 1993); C.A. App. 126.

[12] *Hearing: Subcommittee on Health of the House Comm. On Ways and Means*, 104th Cong., 1st Sess. 7 (Mar. 21, 1995) (Statement of Assistant Sec'y for Health Philip Lee) (hereinafter *Lee Statement*).

[13] "It is true that Congress anticipated that the formulation of nationwide practice guidelines by the medical community through the mechanism of the panels would provide HCFA officials with a basis for improving the quality of services and conserve expenditures under Medicare and Medicaid." C.A. App. 226.

and others." AHCPR, HHS, *Report to Congress: Progress of Research on Outcomes of Health Care Services and Procedures* AHCPR 91-0004, at ES-2 (1995).[14] In sum, these representations of government officials prove that HCFA will rely on the recommendations contained in CPGs.

Perhaps the most compelling proof that federal officials will rely on recommendations in CPGs can be found in a report issued by AHCPR shortly before the D.C. Circuit issued its decision in this case. *Better Quality* Can *Cost Less: The Evolving Role of AHCPR* (July 21, 1995) (hereinafter *AHCPR's Role*). There, AHCPR conceded that Congress foresaw that federal policymaking officials would use CPGs' advice. As AHCPR explained, *id.* at 6, 31 (emphasis added):

> Because they perform distinct yet complementary functions, *AHCPR and [HCFA] often work as a team to improve the quality and cost-effectiveness of care to Medicare beneficiaries. The goal is to create a series of performance measures that can be used by HCFA*, the local Peer Review Organizations (PROs), and providers themselves to monitor and improve quality. In working toward this goal, AHCPR has

[14] The government also supplies health care to individuals through the activities of, for example, the Departments of Veterans Affairs (DVA), Defense, and Interior. HHS recently noted that, in collaboration with the Rand Corporation, DVA "will test guideline-based review criteria for use in VA hospitals throughout the U.S." 9 Department of Health and Human Services, *Fiscal Year 1996—Justification of Estimates for Appropriations Committees: Public Health Service and Agency for Health Care Policy and Research*, at 50 (hereinafter *HCFA 1996 Appropriations*). Because such government physicians and programs themselves are part of the medical profession, the government was one of the intended recipients of the medical advice contained in the Low Back CPG. This means, of course, that AHCPR in fact *did* establish the Low Back Panel for the purpose of advising government officials, even if those officials only administer health care to individual patients, rather than formulate our national health care policy.

> been providing the scientific foundation through its guidelines and medical effectiveness research, and HCFA and the PROs have been building on this knowledge base to develop specific performance measures.
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> * * * *
>
> *All players in the health care system*—employers, insurers, providers, and consumers *as well as Federal and State policymakers*—seek objective, science-based information to make critical decisions about how to allocate resources and how to provide the best possible care. While this reliance on information has always been present, dramatic changes in the health care environment have sharpened this need. *More than ever before, decisionmakers in the public and private sectors want to balance the need to control health care spending with the desire to address consumer concerns about preserving quality, choice, and coverage.*

AHCPR also identified a specific program in which HCFA has relied on CPGs, *id.* at 6:

> One broad initiative in this effort is the Medicare Quality Indicator System (MQIS), which is developing quality of care indicators for the full range of services provided to Medicare beneficiaries. *In building the MQIS, and in conducting other standard-setting and monitoring activities, HCFA is making extensive use of AHCPR-sponsored clinical practice guidelines and PORTs.*[15]

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[15] AHCPR's report gave the following examples, *AHCPR's Role* 6:

> "• **Acute myocardial infarction and ischemic heart disease.** HCFA is developing and testing treatment quality indicators and is building on two AHCPR-funded PORTs, "Consequences of Variation in Treatment for Acute Myocardial Infarction," and "Outcome Assessment Program in Ischemic Heart Disease." Similarly, AHCPR's research on ischemic heart disease is forming the basis of the work HCFA is doing to develop quality indicators in the use of

AHCPR also recognized that Congress intended that the CPG process overseen by AHCPR would play this valuable role.

2. The D.C. Circuit gave no weight to that evidence because, it said, "there is nothing in the record to show that *at the time that the Low Back Panel was appointed* HCFA or any other federal agency intended to use the Panel's guidelines as recommendations to formulate policy." App. 13a (emphasis added). That ruling, however, is clearly flawed in several respects.

First, the OBRA provisions discussed above supply a complete answer to the D.C. Circuit's concern, for two complementary reasons. On the one hand, "[t]he best evidence of [congressional] purpose is the statutory text adopted by both Houses of Congress and submitted to the President," *West Virginia Univ. Hosps. v. Casey*, 499 U.S. 83, 98 (1991), while, on the other hand, agencies are presumed to follow the law, *Department of State v. Ray*, 502 U.S. 164, 176 (1991); *Citizens to Preserve Overton Park v. Volpe*, 401 U.S. 402, 414 (1971). Since OBRA directed AHCPR and HCFA to work together in the CPG program to reduce Medicare costs, the presumption (unrebutted in this case) is that AHCPR and HCFA carried out that assignment and that each profited from their collaboration. The available evidence supports that

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percutaneous transluminal coronary angioplasty (PTCA) and coronary artery bypass graft (CABG) procedures.

"• **Benign prostatic hyperplasia.** AHCPR's clinical practice guideline on benign prostatic hyperplasia has been the basis for a national quality indicator module that HCFA is pilot testing.

"• **Hospital quality indicators.** AHCPR recently supported research to develop quality indicators for hospital care. The project goal is to better identify complications of treatment using the discharge data set. The primary investigator for the project is now advising HCFA regarding data to be collected, data collection techniques and analysis, tools for local interpretation of data, and strategies for disseminating information."

conclusion.[16] *Yet in deciding whether the government would utilize CPGs' recommendations, the D.C. Circuit ignored the provisions of OBRA discussed above expressly directing the government to make use of CPGs in the Medicare program.* That was a clear error. Because OBRA existed, in the D.C. Circuit's words, "at the time that the Low Back Panel was appointed," App. 13a, that court ignored the most probative evidence available showing that Expert Panels are utilized, at least in part, for the purpose of advising the government.

Second, the D.C. Circuit went wrong even when it limited its focus to the record in this case. The unrebutted evidence cited above proves that AHCPR intended to make use of Low Back Panel's CPG when that panel was created, even if those statements were uttered afterwards. Certainly, the D.C. Circuit could not have meant that those statements are immaterial because they were uttered after the Low Back Panel was created; otherwise, the confessions of all but the most extraordinary suspects would have to be excluded from evidence as irrelevant, since they are given *after* the crime has been committed. Finally, the D.C. Circuit overlooked the procedural posture of this case. In district court it was the *government's* burden, not petitioner's, to adduce the type of evidence adumbrated by the court of appeals, since it was the *government* that moved for summary judgment on the ground that FACA was inapplicable. As movant, the government therefore had the burden under Rule 56, Fed. R. Civ. P., of proving that it could not have had the intent of using the Low Back Pain CPG when that panel was launched. *See, e.g., Celotex Corp. v. Catrett*, 477 U.S. 317 (1986). The only evidence offered by the government supports the inference that the government knew that CPGs can and would be used by HCFA. *See* C.A. App. 272.

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[16] Physician Payment Review Comm'n, *Annual Report to Congress* 375 (1995) ("[i]n selecting topics for guideline development, the agency considers several criteria," including "the needs of Medicare and Medicaid beneficiaries").

II. THE QUESTIONS PRESENTED ARE IMPORTANT

The questions presented will recur with the degree of regularity necessary to justify review by this Court. AHCPR already has supervised the work of numerous Expert Panels. As of August 1994, AHCPR had commissioned 22 Expert Panels, including the Low Back Panel that developed the CPG on Acute Low Back Problems in Adults. The CPG issued by that Panel was the 16th such report in an ongoing series of publications.[17] AHCPR also commits extensive resources to the publication and distribution of CPGs and allied materials.[18] AHCPR believes that this process should continue due to the importance of the program to federal health care policy.[19]

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[17] Other CPGs include *Cataract in Adults: Management of Functional Impairment* (Feb. 1993); *Urinary Incontinence in Adults* (Mar. 1992); *Heart Failure: Evaluation and Care of Patients with Left Ventricular Systolic Dysfunction* (Mar. 1994); *Unstable Angina: Diagnosis and Management* (Mar. 1994); *Pressure Ulcers in Adults: Prediction and Prevention* (May 1992); *Acute Pain Management: Operative or Medical Procedures and Trauma* (Feb. 1992); *Benign Prostatic Hyperplasia: Diagnosis and Treatment* (Feb. 1994); *Management of Cancer Pain* (Mar. 1994); and *Depression in Primary Care: Volume 1 (Detection and Diagnosis)* and *Volume 2 (Treatment of Major Depression)* (Apr. 1993). Not surprisingly, those CPGs apply to areas of major concern to the Medicare program.

[18] As of April 1994, AHCPR had disseminated 8.5 million guideline publications. AHCPR makes CPGs widely available to consumers, physicians, and health care providers, and also sends each newly released CPG to ranking officials in public agencies and in Congress. Each CPG is sent to and used by the Surgeon General of the United States, HCFA, and the Directors or Administrators of the seven other agencies in the Public Health Service, including the Center for Disease Control and the National Institutes of Health. CPGs also are sent to leading health officials in the Departments of Defense and Veterans Affairs and the Office of Management and Budget. Sofamor Danek Motion for Summary Judgment Exs. 9, 10.

[19] *See AHCPR's Role* 1, 5-7, 31; *HCFA 1996 Appropriations* 50, 69; General Accounting Office, *Practice Guidelines: Overview of*

Accordingly, the questions presented by this case will have considerable continuing practical importance.

The questions presented also are of sufficient importance to warrant review by this Court. Each year, Americans spend more than $1 trillion on health services, and the federal government spends billions of dollars on the Medicare program.[20] AHCPR believes that CPG's will play a critical role in reducing Medicare costs. In the words of former AHCPR Administrator J. Jarrett Clinton, AHCPR "serves as a compass to an enormous investment measured in billions of dollars."[21] AHCPR has said that Expert Panels and PORTs address 10 of the 15 most costly diagnoses for which Medicare patients are hospitalized, and that their work can materially assist federal health care policymakers. *AHCPR's Role* 6-7, 31. AHCPR has said that it supports research in numerous areas of concern to contemporary health care reform, such as managed care, cost-effectiveness in community care for the elderly, and rural health care.[22] Moreover, AHCPR's work in the CPG process alone is costly. The process of developing, drafting, and distributing CPGs comes at considerable public expense. During the past two years, AHCPR spent $4.6 million to distribute CPGs and their accompanying materials, and it estimates that

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Agency for Health Care Policy and Research Efforts: Testimony Before Subcom. On Health of the House Comm. On Ways and Means 8, 11 No. AO/T-HEHS-95-221 (July 25, 1995); *Lee Statement* 11-18 (all describing new AHCPR projects); *see also Vladek Statement* 12.

[20] *Lee Statement* 5.

[21] *Part 3: Department of Health & Human Services Public Health Service: Hearings Before the Subcomm. on the Department of Labor, Health & Human Services, Education and Related Agencies of the House Comm. on Appropriations*, 103d Cong., 2d Sess. 899, 900 (1994) (testimony of AHCPR Adm'r Clinton) [hereinafter *1995 Appropriations Hearings*].

[22] *1995 Appropriations Hearings* 899 (testimony of AHCPR Adm'r Clinton).

it will spend an additional $2.5 million on that effort during 1995.[23] On the Low Back Panel alone AHCPR spent at least $928,711.40, excluding the additional funds needed for dissemination of the Low Back CPG and its accompanying documents. C.A. App. 268.[24] In sum, measured by their projected dollar effect alone, the role of CPGs in the contemporary development of patient treatment and national health care policy makes critical the need to ensure their unbiased creation.

The D.C. Circuit interpretation of FACA defeats the usefulness of that law in this setting. The facts of this case underscore those concerns. Because of the increasing longevity of the American public, the crushing costs of in-patient hospital care, and the projected bankruptcy of Medicare in the next century, for the last three years a (if not *the*) principal subject of domestic public debate has been the formulation of national health care policy. There is no doubt that the government believes that CPGs in fact will supply valuable recommendations to officials at HHS administering Medicare, since AHCPR itself has promoted CPGs for that purpose. There is no doubt that officials at HHS in fact will rely on Expert Panels' recommendations to formulate Medicare policy, since the government has *never* denied it; indeed, those officials would be foolish not to do so. And if those two propositions are true, then there is no good reason for allowing Expert Panels to escape their duty to comply with FACA. Yet, the D.C. Circuit absolved the government from compliance with FACA on the basis of two grounds that trivialize the effect of that law: namely, (1) in OBRA Congress did not expressly identify the federal government as an intended beneficiary of the

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[23] *1995 Appropriations Hearings* 899, 964-65 (testimony of AHCPR Adm'r Clinton).

[24] AHCPR estimates that each CPG costs approximately $1.5 million to develop and an additional $200,000-$500,000 to print and disseminate. *1995 Appropriations Hearings* 809, 909.

"advice or recommendations" of Expert Panels—even though there is no doubt that Congress designed the CPG program for that purpose, among others—and (2) Congress or the Executive did not expressly announce its intent to "utilize" the work of this Expert Panel before this panel was launched—even though the statute and unrebutted evidence proves that this panel in fact will be so used. By allowing AHCPR to avoid its responsibility of compliance with FACA for all Expert Panels, the D.C. Circuit has denied the public the benefit of scrutiny of the entire CPG process, a denial that would come at little or no cost to the government.

Finally, it would be a mistake to await the further development in the lower courts of the questions presented by this case. Litigation under FACA traditionally has been undertaken in the D.C. Circuit, so that court's decision in this case effectively may serve as the only circuit court decision on the issue. Mindful of the fact that litigation under statutes like the FACA often focuses exclusively (or virtually so), in the D.C. Circuit, in the past this Court has reviewed decisions by the D.C. Circuit involving laws similar to FACA, such as the FOIA, even though that court was the only circuit to have addressed the precise issue.[25] The same course is appropriate in this case. The harms caused by the decision below to both the FACA process and the CPG development process mitigate against waiting until a circuit conflict develops on the precise issues presented by this case.

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[25] *E.g., Department of Justice v. Tax Analysis*, 492 U.S. 136 (1989); *Department of Justice v. Reporters Committee for Freedom of the Press*, 489 U.S. 541 (1991); *cf. Department of State v. Ray*, 502 U.S. 164 (1991) (only the Eleventh Circuit had considered the precise question presented).

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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APPENDICES

APPENDIX A

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued May 9, 1995 Decided August 4, 1995

No. 94-5356

SOFAMOR DANEK GROUP, INCORPORATED,
Appellant

v.

CLIFTON R. GAUS, ADMINISTRATOR,
AGENCY FOR HEALTH CARE POLICY AND RESEARCH,
DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*,
Appellees

Appeal from the United States District Court
for the District of Columbia
(No. 94cv01120)

Before: EDWARDS, *Chief Judge*, ROGERS and TATEL, *Circuit Judges*.

Opinion for the court filed by *Circuit Judge* ROGERS.

ROGERS, *Circuit Judge*: The court must decide whether a panel of experts and consumers convened by the Agency for Health Care Policy and Research to develop a clinical practice guideline on the treatment of lower back pain for health care practititioners was an "advisory committee" under the Federal Advisory Committee Act, 5 U.S.C. App. §§ 1-15 ("FACA"). Appellant Sofamor Danek, Inc. maintains that the Low Back Panel was an

advisory committee and that the federal government must discontinue distribution of and reliance on the *Clinical Practice Guideline on Acute Low Back Problems in Adults* because it was not developed in compliance with FACA requirements. The district court granted summary judgment for appellees, ruling that the Low Back Panel was not a FACA advisory committee because it was not established or utilized "in the interest of obtaining advice or recommendations for . . . the Federal Government." 5 U.S.C. App. § 3(2). We affirm.

I.

The Low Back Panel was established pursuant to the Omnibus Budget Reconciliation Act of 1989, Pub. L. No. 101-239, § 6103, 103 Stat. 2106, 2189-2208 ("OBRA"). As part of OBRA, Congress created the Agency for Health Care Policy and Research ("Research Agency").[1] Congress gave the Research Agency a mandate to improve health care "through the establishment of a broad base of scientific research and through the promotion of improvements in clinical practice . . . and in the organization, financing, and delivery of health care services."[2] The Research Agency is to arrange for:

> the development and periodic review and updating of—
>
> (1) clinically relevant guidelines that may be used by physicians, educators, and health care practitioners to assist in determining how diseases, disorders, and other health conditions can most effectively and appropriately be prevented, diagnosed, treated, and managed clinically; and

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[1] The Research Agency is part of the Public Health Service in the Department of Health and Human Services. 42 U.S.C. §§ 202, 299(a). Many of its responsibilities for developing guidelines are carried out by the Office of the Forum for Quality and Effectiveness in Health Care ("the Forum"). *Id.* § 299b. For ease of reference, we generally refer to the Research Agency.

[2] *Id.* § 299b.

> (2) standards of quality, performance measures, and medical review criteria through which health care providers and other appropriate entities may assess or review the provision of health care and assure the quality of such care.[3]

To accomplish this goal, Congress authorized the Research Agency both to contract with public and private nonprofit entities and to convene panels of experts and consumers.[4] When the Research Agency convenes a panel, it publicly seeks nominations and then selects the members of the panel after consultation with interested individuals and groups.[5] The panel members must include physicians and health care practitioners representing varying interests, including relevant specialities, as well as two persons who do not derive their livelihood from treating the health condition addressed.[6] While the Research Agency determines the health condition that the clinical practices guideline will address, the panel determines the scope and content of the guideline; neither the Research Agency nor anyone in the Department of Health and Human Services ("HHS") can modify or disapprove the guideline developed by a panel.[7] The Research Agency's

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[3] *Id.* § 299b-1(a).

[4] *Id.* §§ 299b-1(c), -2(a).

[5] *Id.* § 299b-2(c).

[6] *Id.*

[7] *Id.* § 299b-3(a)(1)(A). The House Report on OBRA noted that:

> There is a broad consensus that the Federal government should not develop these guidelines. The [Research Agency] satisfies this concern, since no one in the [Research Agency] or the Department of HHS would have any authority to review, modify, approve or disapprove the guidelines developed by panels or contractors. On the other hand, the Committee believes it is essential that there be a focal point for this activity and that a Federal official be held accountable to make sure the activity is carried out properly.

H.R. REP. No. 247, 101st Cong., 1st Sess. 378, *reprinted in* 1989 U.S.C.C.A.N. 1906, 2104.

role is to support the process for development and periodic review of the guidelines,[8] ensure that the panels use an evidence-based methodology,[9] publish and disseminate the guidelines,[10] pilot test them in a clinical setting,[11] and evaluate their effect on the clinical practice of medicine.[12]

Pursuant to this statutory scheme, the Research Agency established a twenty-three member panel to develop a clinical practice guideline for low back disorders.[13] Thereafter, the Low Back Panel held a public meeting to allow interested persons to present information orally and in writing.[14] Sofamor Danek, a manufacturer of medical devices used in back surgery, declined to participate despite an invitation from the Research Agency to provide information to the Panel. The Panel ultimately developed the *Clinical Practice Guideline on Acute Low Back Problems in Adults,* which was published on December 8, 1994. Sofamor filed suit for declaratory and injunctive relief, and the district court granted summary judgment for appellees. Sofmar Danek appeals; our review is *de novo.*[15]

II.

Congress enacted FACA in 1976 to address problems created by the "numerous committees, boards, commissions, councils, and similar groups which have been established to advise officers and agencies in the executive branch. . . ." [16] The statute has two principal purposes:

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[8] 42 U.S.C. §§ 299b-1(a)(1), -2(a).

[9] *Id.* § 299b-1(b)(1).

[10] *Id.* § 299b-3(c).

[11] *Id.* § 299b-3(d).

[12] *Id.* § 299b-3(e).

[13] 56 Fed. Reg. 11,452-11,453 (March 18, 1991).

[14] 57 Fed. Reg. 32,991-32,992 (July 24, 1992).

[15] *Tao v. Freeh,* 27 F.3d 635, 638 (D.C. Cir. 1994).

[16] 5 U.S.C. App. § 2(a).

"to enhance the public accountability of advisory committees established by the Executive Branch and to reduce wasteful expenditures on them."[17] *Public Citizens v. United States Dep't of Justice*, 491 U.S. 440, 459 (1989). FACA defines an advisory committee as:

> any committee, board, commission, council, conference panel, task force, or other similar group, or any subcommittee or other subgroup thereof . . . which is—
>
> (A) established by statute or reorganization plan, or
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> (B) established or utilized by the President, or
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> (C) established or utilized by one or more agencies,
>
> *in the interest of obtaining advice or recommendations* for the President or one or more agencies or officers of the Federal Government. . . .[18]

Notwithstanding the "almost unfettered breadth" of this definition, *Public Citizen*, 491 U.S. at 452 n.8, Congress did not intend for FACA to apply to "every formal and informal consultation between the President or an Executive agency and a group rendering advice." *Id.* at 453. In considering a committee of the American Bar Association, the Supreme Court had occasion to interpret narrowly the phrase "establish or utilize" to encompass only those advisory committees established by or for an agency.

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[17] Thus, FACA requires that an advisory committee file a charter, § 9(c); have members [who] are "fairly balanced in terms of the points of view represented and the functions to be performed," § 5(b)(2); give advance notice of its meetings, which shall be open to the public, § 10(a)(1) & (2); and keep minutes of its meetings, § 10(c), which, along with reports and records, are to be available to the public unless excepted under the Freedom of Information Act, § 10(b). It is undisputed that the Low Back Panel did not comply with FACA's public access requirements.

[18] *Id.* § 3(2) (emphasis added).

See id. at 462. In so doing the Court made clear that mere subsequent and optional use of the work product of a committee by a federal entity does not involve utilization under FACA. *Id.* at 452. The Court noted that under FACA § 2(b)(6), the work of an advisory committee is to be "exclusively advisory in nature." *Id.* at 446.

Sofamor Danek contends that the Low Back Panel was established by OBRA, and that the *Clinical Practice Guideline on Acute Low Back Problems in Adults* will be utilized by federal agencies and officials, including the Research Agency and the Health Care Financing Administration ("HCFA"), which administers the Medicare and Medicaid programs. Therefore, Sofamor Danek maintains, the Panel was established and utilized, at least in part, in the interest of obtaining advice for HCFA, and appellees should be enjoined from further dissemination of the *Guideline* and any reliance on it. Because the Low Back Panel was established by the federal government within the meaning of FACA, the dispositive issue as to establishment is whether the Panel's purpose was to provide "advice or recommendations" to HCFA or other federal entities. In light of Congress' stated purpose for the clinical practice guidelines and the absence of evidence of additional, unstated purposes, and because we find no convincing evidence that HCFA or any other agency "utilized" the Low Back Panel to obtain "advice or recommendations," we conclude that FACA does not apply to the Low Back Panel that developed the *Guideline on Acute Low Back Pain in Adults.*

Congress stated in OBRA that it created a system for developing clinical practice guidelines in order to "promot[e] the quality, appropriateness, and effectiveness of health care. . . ." [19] Toward that end, OBRA instructed the Research Agency (through the Forum) to develop guidelines that "may be used by physicians, educators, and

[19] 42 U.S.C. § 299b-1(a).

health care practitioners to assist in determining how diseases, disorders, and other health conditions can most effectively and appropriately be prevented, diagnosed, treated, and managed clinically."[20] The statute requires the guidelines to be "in formats appropriate for use by physicians, health care practitioners, providers, medical educators, and medical review organizations and in formats appropriate for use by consumers of health care. . . ."[21] This purpose is reflected as well in the legislative history, which states that "the guidelines are intended to help physicians provide services in a more effective and appropriate manner."[22] The Research Agency implemented the statutory purpose when it prepared program notes for the panels and, specifically, when it announced the creation of the Low Back Panel for the purpose of developing "clinically relevant guidelines that may be used by physicians, educators, and health care practitioners."[23] For these reasons, we agree with appellees that Congress authorized, and the Research Agency created, the Low Back Panel to provide advice to private health care practitioners, and not to the federal government. *Cf. Center for Auto Safety v. Cox*, 580 F.2d 689, 692-93 (D.C. Cir. 1978) (distinguishing between a committee that exists in significant part "to offer advice, often solicited, to the federal government," and a mere "clearinghouse for the transmission of views and ideas") (citation omitted).

Sofamor Danek does not dispute that one purpose of the Low Back Panel was to provide advice for physicians and health care professionals outside the federal govern-

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[20] *Id.* § 299b-1(a)(1).

[21] *Id.* § 299b-1(b)(2).

[22] H.R. REP. No. 101-247, at 378, 1989 U.S.C.C.A.N. at 2104.

[23] 56 Fed. Reg. at 11,452; *accord* 57 Fed. Reg. at 32,991 (notice of public meeting); *see also Research Agency Program Note: Clinical Practice Guideline Development* 1 (August 1993).

ment. Rather, it contends that Congress, in authorizing the panels in OBRA, had the additional purpose of providing advice to the HHS Secretary regarding Medicare reimbursement policy, and that this purpose makes FACA applicable to the Low Back Panel. Sofamor Denek relies on several OBRA provisions indicating that Congress intended the panels to address medical conditions of importance to the Medicare program. Thus, OBRA requires the Research Agency to consult with HCFA in setting an agenda for the development of guidelines on specific health problems.[24] OBRA also requires the Research Agency to develop initial guidelines by January 1, 1991, for at least three "clinical treatments or conditions that [*inter alia*] account for a significant portion of expenditures under [the Medicare program]," [25] and a set of guidelines by January 1, 1996, "that address the prevention of not fewer than three conditions that account for significant national health expenditures." [26] In addition, OBRA requires the HHS Secretary to assure that the panels' activities appropriately reflect the priorities of Medicare, at least in part through consultation with HCFA.[27]

Sofamor Danek's dual-purpose contention fails to appreciate the distinction noted by Congress when enacting

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[24] 42 U.S.C. § 299b-3(a)(2)(B).

[25] *Id.* § 1320-12(a)(3)(A); *accord id.* § 299b-1(d).

[26] *Id.* § 299b-1(f).

[27] *Id.* §§ 299b-1(e), 299b-3(a)(2)(B), 1320b-12(a)(1)(B), 1320b-12(b)(3). *See also* 60 Fed. Reg. 26,886, 26,886 (May 19, 1995) (criterion in determining health conditions to be addressed by the guidelines is "the economic burden posed by the prevention, diagnosis, treatment, and clinical management of a health condition, including the impact on publicly funded programs"); 58 Fed. Reg. 49,308-49,309 (September 22, 1993) (same); *Research Agency Program Note: Clinical Practice Guideline Development* 2 (August 1993) ("[s]pecific needs of the Medicare and Medicaid populations" is one factor in selecting guideline topics).

FACA between the purpose for establishing a committee and the government's subsequent and optional use of a committee's work product. In terms used by Congress, the Low Back Panel is operational, developing guidelines for health care practitioners, rather than advisory to the federal government, and so not covered by FACA.[28] The OBRA provisions referring to the Medicare program on which Sofamor Danek relies merely indicate that Congress intended the clinical practice guidelines to address health conditions of importance to the Medicare program. It does not necessarily follow, as Sofamor suggests, that Congress intended a panel like the Low Back Panel to provide advice to HCFA and other government entities. Advice on the agenda for the development of guidelines flows from HCFA to the Research Agency; Sofamor Danek points to nothing in the statute that requires HCFA to consider the *Clinical Practice Guideline on Acute Low Back Problems in Adults* in developing Medicare reimbursement policy. To the extent that health care practitioners use the *Guideline* to treat more efficiently health conditions for which Medicare expends substantial funds, the *Guideline* presumably will benefit the Medicare

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[28] *See* H.R. REP. No. 1017, 92d Cong., 2d Sess. 4, *reprinted in* 1972 U.S.C.C.A.N. 3491, 3494 ("The term advisory committee as used in this bill does not include committees or commissions which have operational responsibilities. Only those committees established for the purpose of obtaining advice are within the bill's definition."); S. REP. No. 1098, 92d Cong., 2d Sess. 8 (1972) (if a committee is "primarily operational, rather than advisory," it is not covered by FACA); 41 C.F.R. § 101-6.1004(g) (same); *see also Natural Resources Defense Council v. EPA*, 806 F. Supp. 275, 278 (D.D.C. 1992); *Public Citizen v. Commission on the Bicentennial*, 622 F. Supp. 753, 758 (D.D.C. 1985); *HLI Lordship Indus., Inc. v. Committee for Purchase from Blind and Other Severely Handicapped*, 615 F. Supp. 970, 978 (E.D. Va. 1985) (ruling FACA inapplicable to committee whose "advisory capacity is secondary to its operational activities"), *rev'd on other grounds*, 791 F.2d 1136 (4th Cir. 1986).

program.[29] Indeed, the extent of this effect appears to be what Congress wanted to determine when it instructed the Research Agency to report on the impact of the initial guidelines on at least three health conditions which account for significant Medicare expenditures or otherwise meet the needs and priorities of the Medicare program.[30] Thus, in creating the guideline system, the Medicare program could benefit without any officer or agency of the federal government obtaining "advice or recommendations."

Congress expressly stated the purpose for the establishment of the panels—improving health care by developing, reviewing, and updating guidelines for use by clinical health care practitioners.[31] In light of that express purpose, the court will not lightly infer any other purpose, such as reducing health care costs by giving advice to the Secretary regarding Medicare reimbursement policy. *Cf. Cipollone v. Liggett Group Inc.*, 112 S. Ct. 2608, 2618 (1992) ("Such reasoning is a variant of the familiar principle of *expressio*[] *unius est exclusio alterius:* Congress' enactment of a provision defining the pre-emptive reach of a statute implies that matters beyond that reach are not pre-empted."); *Freightliner Corp. v. Myrick*, 115 S. Ct. 1483, 1488 (1995) (inference discussed in *Cipollone* is rebuttable). Although HCFA may consult the *Clinical Practice Guideline on Acute Low Back Problems in Adults* when setting Medicare reimbursement policy,[32]

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[29] *See* 58 Fed. Reg. 12,042-12,043 (March 2, 1993) (HCFA, through contracts with Peer Review Organizations, attempts to "eliminate unreasonable, unnecessary and inappropriate care provided to Medicare beneficiaries" and to ensure that Medicare services meet "professionally recognized standards of health care.").

[30] 42 U.S.C. § 120b-12(a)(3).

[31] *Id.* § 299b-1(a).

[32] Thomas Hoyer, the Acting Director of the Office of Coverage and Eligibility Policy in the Bureau of Policy Development in HCFA, stated that in examining "the widest possible scope of information and opinion," HCFA "may also review clinical practice

and Congress may have intended that HCFA do so,[33] it does not follow that Congress' purpose in authorizing the panels to develop a clinical practice guideline like the *Guideline on Acute Low Back Problems in Adults* was to provide advice or recommendations to the Secretary or HCFA. Had Congress stated in the statute that the clinical practice guidelines were designed to provide advice or recommendations regarding HCFA policy, Sofamor Danek would likely have a stronger case. But neither Congress nor the Research Agency identified such a purpose for the Low Back Panel. Absent that, Sofamor Danek's argument that Congress' unstated purpose was for the *Clinical Practice Guideline on Acute Low Back Problems in Adults* to function as advice or recommendations to HCFA is met by the express statement of Congressional purpose.[34]

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guidelines, including those developed under the sponsorship of [the Research Agency]. . . ." Joint Appendix at 273.

[33] The OBRA Conference Report states, in regard to establishment of the Research Agency, that:

> The conferees intend, that to the extent appropriate, the Secretary use the information and practice guidelines . . . to enhance the quality of care provided through [Medicare and Medicaid]. The Secretary shall also assimilate the research findings, practice guidelines and other information . . . to improve the efficiency and effectiveness of the Medicare and Medicaid programs.
>
> The conferees intend that the research findings and guidelines . . . be reflected in the . . . payment determinations, and other utilization review activities. Further, it is intended that the Secretary ensure that the research and guidelines programs be responsive to the needs and priorities that may arise from implementation of physician payment reform under this Act.

H.R. CONF. REP. No. 386, 101st Cong., 1st Sess. 893, *reprinted in* 1989 U.S.C.C.A.N. 3018, 3496.

[34] *See Nader v. Baroody*, 396 F. Supp. 1231, 1234 (D.D.C. 1975) (only committees "directed to make recommendations on an identified governmental policy for which specified advice was being

Put otherwise, Sofamor Danek's dual-purpose contention confuses the specific ills on which FACA is focused —the existence of advisory committees involving "the wasteful expenditure of public funds for worthless committee meetings and biased proposals," *Public Citizen*, 491 U.S. at 453—with the use by federal entities of data specifically developed for another purpose. That HCFA, subsequent to the deliberations of the Panel, considers a clinical practice guideline does not show that the Low Back Panel was "established or utilized . . . in the interest of obtaining advice or recommendations for . . . the Federal Government."[35] Earlier decisions by both the Supreme Court and this court, in considering an entirely private organization, a government contractor, and an Article III entity, have interpreted the term "utilized" in FACA narrowly, to mean "something along the lines of actual management or control of the advisory committee." *Washington Legal Foundation v. United States Sentencing Comm'n*, 17 F.3d 1446, 1450 (D.C. Cir. 1994) (Article III entity); *see also Public Citizen*, 491 U.S. at 461-62 (Committee of the American Bar Association); *Food Chemical News v. Young*, 900 F.2d 328, 332-33 (D.C. Cir.) (private contractor), *cert. denied*, 498 U.S. 846 (1990).[36] When "utilized" is so defined, FACA can only

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sought" are subject to FACA); *Public Citizen v. Commission on the Bicentennial*, 622 F. Supp. at 757-58 (committee primarily operational where the statute does not refer to it as an advisory committee and its enumerated duties do not include providing advice or recommendations to the federal government).

[35] 5 U.S.C. App. § 3(a).

[36] Amicus' contention that this narrow definition of "utilize" is confined to circumstances where a court seeks to avoid a difficult constitutional issue, *see Public Citizen*, 491 U.S. at 465-67; *Association of Am. Physicians & Surgeons, Inc. v. Clinton*, 997 F.2d 898, 906 (D.C. Cir. 1993) (dictum), is unpersuasive in light of *Food Chemical News*, 900 F.2d at 332-33, where the court concluded that the Public Citizen definition of "utilize" was controlling despite the absence of a constitutional issue.

apply if the committee is established, managed, or controlled for the purpose of obtaining advice or recommendations for the federal government. Here the only entities which have arguably established, managed, or controlled the Low Back Panel are Congress and the HHS Secretary through the Research Agency, so it is their intent that controls. But even if "utilization" does not require control in every instance, as where a committee is authorized by Congress and appointed and funded by an executive branch agency, there is nothing in the record to show that at the time the Low Back Panel was appointed HCFA or any other federal agency intended to use the Panel's guidelines as recommendations to formulate policy. Again, mere subsequent and optional use of the guideline work product by HCFA or another federal agency does not implicate FACA.

Consequently, in view of the express statement by Congress on the purpose of the clinical practice guidelines, and the reflection of that purpose by the Research Agency in convening the Low Back Panel, the court has no occasion to infer another intent by Congress or the HHS Secretary. That the *Guideline* may, in turn, be considered along with other data in the administration of the Medicare program or other federal programs is a secondary effect of Congress' decision that guidelines should be developed for clinical health care. It does not, in the absence of Congressional intent (or Research Agency intent) that the *Guideline* function as advice or recommendations to the federal government, or of evidence that HCFA, at the time the Panel was deliberating, intended to use and did, in fact, make use of the Panel's recommendations to formulate policy, make the Low Back Panel a FACA advisory committee.

The conclusion that the Low Back Panel was not intended to provide advice or recommendations to the HHS Secretary or HCFA is supported by comparing it with groups that do constitute FACA advisory committees.

For example, Sofamor Danek maintains that the Low Back Panel is analogous to advisory panels established by the HHS Secretary with respect to the categorization of medical devices, and that we should infer that these panels are covered by FACA because Congress has exempted them from the FACA sunset provision.[37] But the applicability of FACA to the medical devices panels is apparent from Congress' express statement that their purpose is to provide recommendations to the HHS Secretary.[38] By contrast, OBRA and the Research Agency have indicated that the purpose of the Low Back Panel is to develop a clinical practice guideline for the use of health care practitioners, quite apart from any other use that may be made of the *Guideline*. The distinction between the Low Back Panel and a FACA advisory committee is further suggested by the fact that in the same section of OBRA authorizing the guideline panel system, Congress also created the Advisory Council for Health Care Policy, Research, and Evaluation for the purpose of advising the Secretary and providing recommendations to the Research Agency.[39] As with the medical devices panels, Congress acknowledged the applicability of FACA in providing that the Advisory Committee was exempted from FACA's sunset provision.[40] Because Congress knew how to state that it was establishing an advisory committee and did not do so here, the reasonable inference is that it did not intend for FACA to apply to guideline panels. *Cf. Central Bank of Denver v. First Int'l Bank,*

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[37] 5 U.S.C. App. § 14.

[38] Under 21 U.S.C. § 360c(b)(1), the Secretary is authorized to establish panels "[f]or the purpose of securing recommendations with respect to the classification of devices." These panels are exempted from FACA duration limits. *Id.*

[39] OBRA § 6103; 42 U.S.C. § 299c(b)(1) ("The Council *shall advise the Secretary* . . . .") (emphasis added); *id.* § 299c(b)(2) ("Activities of the Council . . . shall include *making recommendations to the [Research Agency]* . . . .") (emphasis added).

[40] 42 U.S.C. § 299c(j).

N.A., 114 S. Ct. 1439, 1448 (1994). Thus, the contrast between the Low Back Panel and the Advisory Council further supports the conclusion that Congress intended a panel like the Low Back Panel to develop guidelines for the use of health care practitioners, with likely secondary uses by federal entities such as HCFA, and not for the purpose of providing advice or recommendations for the federal government. Had another purpose been intended it seems unlikely that Congress would have required, much less that the Research Agency would have sponsored, the *Clinical Practice Guideline on Acute Low Back Problems in Adults* in a format for use by individual decision-makers—physicians, educators, and consumers.

Finally, we are unpersuaded by Sofamor Danek's suggestions that this interpretation of Congress' intent would lead to absurd results. Sofamor Danek suggests that if FACA is inapplicable to the Low Back Panel, an agency can easily circumvent FACA by establishing an advisory committee with a stated purpose other than rendering advice or recommendations to the federal government. The holding in the instant case permits no such subterfuge because it rests on an express statement of congressional intent.[41] Given its power to exempt advisory committees from FACA, Congress has no reason to dissemble about its purpose. It does not necessarily follow that a similar statement of purpose by an agency acting without instruction from Congress would have the same effect; unlike Congress, a federal agency lacks power to exempt advisory committes from FACA and, hence, its motive in characterizing a committee's goal may, depending on the circumstances, be suspect. Here, Congress determined that a clinical practice guideline like the *Guideline on Acute Low Back Problems in Adults* should be developed by and for physicians, educators, and health care practitioners and consumers without the retention of any substantive decision-making authority in the federal govern-

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[41] *See id.* § 299b-1(a)(1).

ment;[42] hence, there was no call for advice or recommendations to be given to the federal government.

Accordingly, we affirm the grant of summary judgment to appellees.

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[42] *See* note 7, *supra*.

APPENDIX B

[Filed Dec. 6, 1994]

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

Civil Action No. 94-1120 (GK)

SOFAMOR DANEK GROUP, INC.,
Plaintiff,

v.

J. JARRETT CLINTON, *et al.*,
Defendants.

MEMORANDUM-OPINION

I. Introduction and Procedural History

This action for declaratory and injunctive relief is brought under the Administrative Procedure Act, 5 U.S.C. § 701 et. seq., the Federal Advisory Committee Act (FACA), 5 U.S.C. app. 2 § 1 et. seq., and the Freedom of Information Act (FOIA), 5 U.S.C. § 552.[1] Plaintiff Sofomor Danek, through wholly-owned subsidiaries, develops and manufactures prescription medical devices used in spinal surgery. Defendant Department of Health and Human Services (HHS)—through the Agency for Health Care Policy and Research (AHCPR), the Forum for Quality and Effectiveness in Health Care (Forum), and the Expert Panel on Low Back Problems in Adults (Low Back Panel)—has completed development of a Clinical

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[1] After Sofamor Danek filed its Complaint, the government complied with Sofamor Danek's request under FOIA. Sofamor Danek therefore is not pursuing that claim. *See* Plaintiff's Motion for Summary Judgment at 4.

Practice Guideline (CPG) on low back problems (Low Back CPG).

In brief, Plaintiff seeks to bar Defendants from publishing, disseminating, or in any way relying on the CPG for Acute Low Back Pain, on the grounds that the CPG has been generated by an expert panel convened and operated in violation of the public-access requirements of the Federal Advisory Committee Act.

Plaintiff filed its Complaint on May 24, 1994. On July 18, 1994, Defendants answered. On August 1, 1994, Plaintiff filed its Motion for Summary Judgment, and Defendants filed their Cross-Motion for Summary Judgment on August 12, 1994. On September 16, 1994, Plaintiff filed an Unopposed Motion to Expedite Consideration of This Matter, and, after Defendants filed a Notice that the Low Back CPG was scheduled to be distributed on December 8, 1994, Plaintiff filed a Motion for Preliminary Injunction as well as a Request for Expedited Hearing. Defendants filed their Opposition to Plaintiff's Motion for Preliminary Injunction on November 30, 1994.

Because the Court finds that the Cross-Motions for Summary Judgment can be decided on the papers and on the case file in its entirety, and that consequently no oral hearing is necessary, the Court denies Plaintiff's Request for an Expedited Hearing (33-1).

Accordingly, this matter is now before the Court upon Plaintiff's Motion for Preliminary Injunction (2-2); Defendants' Motion for Summary Judgment (15-1); and Plaintiff's Motion for Summary Judgment (27-1). The Court has considered the Motions, Oppositions, Replies, and the case file in its entirety, as well as the case law relevant to this action.

For the reasons stated below, Plaintiff's Motions for Preliminary Injunction and for Summary Judgment shall

be denied, and Defendants' Motion for Summary Judgment shall be granted.

II. Statement of Facts [2]

Plaintiff Sofamor Danek, Inc. (Sofamor Danek), through its subsidiaries, develops, manufactures and distributes medical devices, including instruments used in lumbar spinal fusion surgery to treat spinal disorders. Complaint, ¶ 7.

The Agency for Health Care Policy and Research (AHPCR) is an agency of the United States Public Health Service, Department of Health and Human Services. Congress established the AHCPR in the Omnibus Budget Reconciliation Act of 1989 (OBRA), Pub. L. No. 101-239, § 901, 103 Stat. 2189 (1989), which amended the Public Health Service Act, 42 U.S.C. §§ 1301-1395ccc.[3] Congress intended the AHCPR to improve the quality, appropriateness, and effectiveness of health care services, and to improve access to such services. 42 U.S.C. § 299(b). To carry out that objective, Congress directed the AHCPR to facilitate development of CPGs, guidelines that would establish parameters for diagnosing, treating, managing, and preventing selected conditions. 42 U.S.C. § 2(a).

Congress required that the CPGs be based on a comprehensive review of the best scientific research and professional judgment and that they be presented in formats

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[2] The parties filed a Statement of Matetrial Facts Not In Dispute on July 29, 1994. Additionally, the Court treats all facts that were not disputed as conceded pursuant to Federal Rule of Civil Procedure 56 and Local Rule 108(h).

[3] AHCPR was reauthorized and its enabling statute was amended by the AHCPR Reauthorization Act of 1992, Publ. L. No. 102-410, 106 Stat. 2094 (1992). The Reauthorization Act requires that the Forum and each of its CPG panels consider the costs of the CPGs. *Id.* at §§ 5(a)(C)(5) and 5(a)(2).

appropriate for use by physicians, health care practitioners and providers, medical educators, and medical review organizations. 42 U.S.C. § 299b-1(b). The AHCPR defines clinical practice guidelines (CPGs) as "systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances." AHCPR Program Note (August 1993) at 1, Attached as Exhibit 1 to Defendants' Motion for Summary Judgment.

Congress in the OBRA also established the Forum for Quality and Effectiveness in Health Care (Forum). Through the Forum, the AHCPR oversees the development, periodic review and updating of the CPGs. 42 U.S.C. § 299b. Based on the guidelines produced, the Forum oversees development of medical review criteria, standards of quality, and performance measures which assist health care providers to assess or review the provision of health care. AHCPR Program Note, *supra,* at 1.

Congress directed the AHCPR to develop CPGs through the establishment and operation of panels of medical experts and consumers. 42 U.S.C. § 299b-2. The AHCPR facilitates the development of CPGs in two ways: it either itself convenes multidisciplinary private-sector panels of experts and health care consumers, or it contracts with public or private nonprofit organizations to convene panels of experts. AHCPR Program Note, *supra,* at 2.

On March 18, 1991, the AHCPR announced in the Federal Register that it was establishing a panel of experts and health care consumers to develop clinical practice guidelines for low back disorders and related conditions and invited nominations of qualified individuals to serve as chairperson(s) and as panel members. 52 Fed. Reg. 11452 (March 18, 1991).

On April 22, 1992, Dr. James Mason, Assistant Secretary for Health at HHS announced the formation of an AHCPR sponsored 23-member panel of private-sector health care experts and consumers to develop clinical practice guidelines for diagnosing and treating low back problems.

On July 24, 1992, the AHCPR announced in the Federal Register that a public meeting would be held on September 16, 1992 to receive comments and information pertaining to the development of the clinical practice guidelines on Low Back Problems. 57 Fed. Reg. 32991 (July 24, 1992).

Sofamor Danek, by letter from its counsel dated November 1, 1993, informed the AHCPR that it believed the Expert Panels convened to develop clinical practice guidelines, including the Low Back Problems Panel, were advisory committees subject to the procedures and requirements of the Federal Advisory Committee Act (FACA), 5 U.S.C. App. 2.

In a letter to Sofamor Danek dated November 10, 1993, Dr. Jarrett Clinton, then the Administrator of AHCPR, stated that the clinical practice guideline panels are not advisory committees within the meaning of FACA and therefore not subject to FACA's procedural requirements. Representatives of Sofamor Danek and the Department of Health and Human Services met on March 28, 1994. By letter dated April 29, 1994, Beverly Dennis, the Deputy General Counsel at HHS, informed counsel for Sofamor Danek that it continued to be HHS's opinion that the clinical guideline panels are not advisory committees within the meaning of FACA.

After more than two years of work and study, the Low Back Problems Panel has now completed the development of the CPG on low back problems. Along with the CPGs, the AHCPR will publish and disseminate a Quick Reference Guide for Physicians and a Patient's Guide.

The AHCPR will publish and disseminate the CPG on low back problems and its accompanying documents without charge to physicians, health care practitioners and providers, medical educators, and medical review organizations. The CPG on low back problems will also be available through the AHCPR Publications Clearinghouse. Individuals or organizations may call a toll-free number or write the Clearinghouse, and the Clearinghouse will send the CPG, the Clinician's Guide, or the Patient Guide to the requestor without charge. Expenses of the Clearinghouse, the toll-free number, and the printing and dissemination of CPG documents are borne by the AHCPR. Deposition of Carole Hudgings at 83-84; AHCPR Program Note, *supra*, at 4.

The Government has formally notified the Court that it intends to release the Low Back CPG on December 8, 1994.

III. Plaintiff's Motion For Summary Judgment Must Be Denied, and Defendants' Motion for Summary Judgment Must Be Granted

A. *Statutory Background*

Congress enacted FACA in 1972 to control the growth and ensure openness of operation of the "numerous committees, boards, commissions, councils and similar groups which have been established to advise officers and agencies in the executive branch of the Federal Government." 5 U.S.C. App. 2 § 2(a); *see generally Public Citizen v. Department of Justice*, 491 U.S. 440, 466 (1989). To achieve these objectives, the FACA places a number of procedural restrictions on those bodies that constitute "advisory committees." [4] The statute defines an advisory committee as follows:

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[4] Unless the "advisory committee" is composed entirely of full-time federal officers or employees, 5 U.S.C. App. 2 § 3(2)(C)(iii), it must file a detailed charter setting forth its objectives and the scope of its activity, *id.* § 9(c), give advance notice in the Federal

> [A]ny committee, board, commission, council, conference, panel, task force, or other similar group, or any subcommittee or other subgroup thereof (hereafter in this paragraph referred to as "committee"), which is—
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> (A) established by statute or reorganization plan, or
>
> (B) established or utilized by the President, or
>
> (C) established or utilized by one or more agencies,[5]
>
> in the interest of obtaining advice or recommendations for the President or one or more agencies or officers of the Federal Government . . . .
>
> 5 U.S.C. App. 2 § 3(2).

5 U.S.C. App. 2 § 3(2).

Plaintiff makes two arguments that FACA applies in this case. First, Plaintiff argues that the CPG panels were "established by statute"—that is, the OBRA—in the interest of obtaining advice or recommendations. Second, Plaintiff argues that the Low Back Panel will be "utilized" by one or more agencies in the interest of obtaining advice or recommendations. As is explained below, both arguments fail.

Register of any meetings, *id.* § 10(a)(2), hold all meetings open to the public, *id.* § 10(a)(1), keep detailed minutes of each meeting, *id.* § 10(c), make its records available to the public in accordance with the Freedom of Information Act, 5 U.S.C. § 552, *id.* § 10(b), be "fairly balanced in terms of the points of view represented and functions to be performed," *id.* § 5(b)(2), and "not be inappropriately influenced by the appointing authority or by any special interest." *Id.* § 5(b)(3).

[5] "Agency" is defined by reference to the Administrative Procedure Act ("APA"), 5 U.S.C. § 551(1). 5 U.S.C. App. 2 § 3(3). Under the APA, " 'agency' means each authority of the Government of the United States." 5 U.S.C. § 551(1).

B. *The CPG Panels Were Not Established By Statute In The Interest Of Obtaining Advice Or Recommendations*

Although Plaintiff argues that the CPG panels are established by the OBRA, these panels are, in fact, established by the AHCPR. In the OBRA, Congress directed the AHCPR to provide for the development of clinical practice guidelines by expert panels, which can be convened by the Agency itself or by outside contractors. *See* 42 U.S.C. 229b-2(a) OBRA's legislative history confirms this common-sense interpretation: "The Forum can *either* convene panels *or* contract with appropriate groups that satisfy criteria established for this purpose." H.R. Rep. No. 247, 101st Cong.1st Sess. 378, *reprinted in* 1989 U.S. Code Cong. & Admin. News 1906, 2104 (emphasis added) (Plaintiff's Exhibit 23, attached to Plaintiff's Motion for Summary Judgment). The statute is obviously not self-executing. The CPGs constitute the final work product of the panels. The statute gives the Agency discretion to decide whether these panels will be convened by outside contractors or by the Agency itself. Given the fact that Congress gave the Agency the freedom to decide on the procedure to be used in convening the panels, it follows that the panels are to be established by the Agency and have not been established by the statute. If the panels were established by statute, as Plaintiff argues, there would be no point in giving the Agency the discretion which Congress has accorded it with regard to the manner of establishing these panels.

Accordingly, because this Court finds that the CPG panels, including the Low Back Panel, were not established by statute, but were rather established by an agency —the AHCPR—Plaintiff's first argument must fail.

C. *The CPG Panels Were Not Established, And Will Not Be Utilized To Provide Advice To The Federal Government*

Defendants do not dispute that CPG panels are both "established" and "utilized" by "one or more agencies"—that is, the AHCPR. What Defendants do dispute is Plaintiff's argument that the CPG panels are established or utilized "in the interest of obtaining advice or recommendations for . . . one or more agencies or officers of the Federal Government."

The plain language and purpose of the OBRA, together with the record evidence of what the CPG panels do, demonstrate the correctness of Defendants' contention that the low back CPG panel was not established or utilized to render advice to the federal government. Rather, Congress authorized AHCPR to establish CPG panels for the express purpose of advising doctors and other health care practitioners on the appropriate treatment of medical diseases and disorders. Although some federal agencies, after completion of the CPGs, may find them useful for other purposes, such as formulating reimbursement policy, the fact remains that CPG panels are not established for the purpose of advising those federal agencies.

The statutory language in the OBRA makes clear that the CPGs were designed to provide advice to private practitioners, educators and consumers rather than to the federal government. Specifically, the statute defines the CPGs as

> clinically relevant guidelines that *may be used by physicians, educators, and health care practitioners* to assist in determining how diseases, disorders, and other health conditions can most effectively and appropriately be prevented, diagnosed, treated, and managed clinically; . . .

42 U.S.C. § 299b-1(a)(1) (emphasis added). AHCPR's own operative definition of CPGs is consistent with this statutory mandate: "These are systematically developed statements *to assist practitioner and patient decisions* about appropriate health care for specific clinical circumstances." AHCPR Program Note at 1, attached as Exhibit 1 to Defendants' Motion for Summary Judgment (emphasis added).

This conclusion is also borne out by an examination of the Low Back Panel's CPG dissemination Plaintiff seeks to enjoin, a confidential draft of which was submitted to the Court. The Guideline contains absolutely no advice or recommendations for any federal agency or officer in any of its 182 pages. Rather, it summarizes the state of existing research and data on many options for diagnosing and treating low back pain and, based on that research and data, makes treatment recommendations to clinicians. *See, e.g.*, Clinical Practice Guideline: Acute Low Back Problems in Adults (Confidential Review Draft) at 2 (attached as Exhibit 7 to Defendants' Reply Memorandum in Support of their Motion for Summary Judgment and in Opposition to Plaintiff's Motion for Summary Judgment) (stating that the panel divided its findings and recommendations into three chapters "to correlate with the clinical approach: (1) Initial Assessment Methods; (2) Initial Clinical Care Methods; (3) Special Studies and Diagnostic Considerations").

Although Plaintiff correctly notes that several federal agencies, such as the Health Care Finance Administration (HFCA)—an agency within the Department of Health and Human Services that oversees federal spending under the Medicare and Medicaid programs—would potentially utilize the CPG, this is not the purpose for which the CPGs were "established." Rather than focussing on the optional uses that federal agencies may make of the Low Back CPG, FACA requires that the Court inquire into the *intended purpose* of the advice—

that is, whether the advice is directed to the federal government.[6] As the two recent cases cited by Plaintiff demonstrate, it is not important, in determining whether a panel is covered by FACA, whether the federal government actually uses the panel's advice or not, as long as the advice was *directed to* the federal government. *See Alabama-Tombigbee Rivers Coalition v. Department of Interior*, 26 F.3d 1103 (11th Cir. 1994) (affirming the district court's holding that FACA applies to a scientific panel established by the Interior Department to provide advice on whether to list the Alabama sturgeon as an endangered species); *Northwest Forest Resource Council v. Espy*, 846 F. Supp. 1009 (D.D.C. 1994) (holding that FACA applies to the Forest Ecosystem Management Team established by the President for advice in devising a forest management policy).

Here, in contrast, the "advice" generated by expert panels at issue in this case—that is, the Low Back CPG—is not directed to the President or any agency in the federal government. As discussed above, the Low Back CPG contains medical information aimed at educators, doctors and their patients rather than the federal government. This is the task Congress directed the panels to carry out. 42 U.S.C. § 299b-1(a)(1).[7] For this reason, no matter how federal officials might eventually choose to use the Low Back CPG, the Low Back Panel is not an "advisory committee" under FACA.

Finally, this conclusion is supported by the case law. In a case that closely resembles the instant case, another Judge on this bench held that FACA did not apply to a

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[6] To hold otherwise would potentially subject to FACA any type of study, report, text or treatise that might be relied upon by a federal agency.

[7] This Section, quoted on page 10 of this Opinion, makes clear that the purpose of the Guideline is "to assist" the clinical decision-making of "physicians, educators, and health care practitioners." *Id.*

panel of scientists convened by the federal government to offer advice regarding a discrete and narrow scientific question rather than a public policy issue. *Natural Resources Defense Council v. Herrington*, 637 F. Supp. 116, 120 (D.D.C. 1986) (holding that a panel of scientists convened in order to advise the Secretary of Energy on the safety of a particular nuclear reactor did not constitute an advisory committee subject to FACA, as the scientists were convened "merely to examine, from their several perspectives of technical expertise," narrow scientific evidence). As in *Herrington*, this case involves a panel of scientists convened to apply their "technical expertise" to a particular medical issue rather than to any national public policy issues. Consequently, this Court concludes that the Low Back Panel does not constitute an advisory committee under FACA.

IV. Plaintiffs' Motion for Preliminary Injunction Must Be Denied

In order to prevail on an Application for Temporary Restraining Order or a Motion for Preliminary Injunction, the Plaintiff must demonstrate: (1) a substantial likelihood of success on the merits; (2) that irreparable injury will result in the absence of the requested relief; (3) that no other parties will be harmed if temporary relief is granted; and (4) that the public interest favors entry of a temporary restraining order. *Virginia Petroleum Jobbers Ass'n v. Federal Power Commission*, 259 F.2d 921, 925 (D.C. Cir. 1958) (per curiam); *Washington Metropolitan Area Transit Comm'n v. Holiday Tours*, 559 F.2d 841, 843 (D.C. Cir. 1977); *Sea Containers, Ltd. v. Stena AB*, 890 F.2d 1205, 1208 (D.C. Cir. 1989); *National Treasury Employees Union v. United States*, 927 F.2d 1253, 1254 (D.C. Cir. 1991). This Circuit's Court of Appeals has directed the trial court to balance, rather than mechanically apply, these factors. "A stay may be granted with either a high probability of success and some injury, or *vice versa*." *Cuomo v. United States*

Nuclear Regulatory Comm'n, 772 F.2d 972, 974 (D.C. Cir. 1985) (*per curiam*) (emphasis in original); *see also Holiday Tours, supra*, 559 F.2d at 843-44.

Application of the four factors stated above compels the conclusion that Plaintiffs' Motion for Preliminary Injunction must be denied. Plaintiff has failed to meet its burden with regard to each of the stated four requirements.

First, for the reasons discussed above, Plaintiff has failed to demonstrate a substantial likelihood of success on the merits. On the contrary, this Court has concluded that the Low Back Panel does not constitute an advisory committee subject to FACA's requirements.

Second, Plaintiff cannot demonstrate any irreparable harm from publication of the Low Back CPG. In order to establish irreparable injury justifying preliminary injunctive relief, a plaintiff must establish injury that s both "certain and great." *Wisconsin Gas Co. v. F.E.R.C.*, 758 F.2d 671, 674 (D.C. Cir. 1985). The harm claimed by Plaintiff—a potential reduction in the number of "surgical interventions involving spinal fusion performed with medical devices produced by Sofamor Danek" due to the dissemination of the Low Back CPG—is both speculative and remote. *See Mead Johnson Pharmaceutical Group v. Bowen*, 655 F. Supp. 53, 56 (D.D.C. 1986), *aff'd*, 838 F.2d 1332 (D.C. Cir. 1988) (rejecting as "pure speculation" a pharmaceutical company's claim in support of its Motion for Preliminary Injunction that it would suffer loss of sales if a competing generic drug were approved and marketed); *see also Northwest Forest Resource Council v. Espy*, 845 F. Supp. 1009, 1015 (D.D.C. 1994) (concluding that an injunction was not justified where there was no evidence that the recommendations made by an advisory group would have been any different had FACA been complied with by the letter).

Finally, Plaintiff has failed to satisfy the third and fourth requirements for the entry of a preliminary injunc-

tion, as the relief it seeks would substantially harm both Defendants and the public interest. In seeking to enjoin the distribution of this Guideline and its accompanying explanatory materials, Plaintiff requests that the Court prevent the government from sharing with the public a source of state-of-the-art medical knowledge that would be of immediate use in treating an ailment that afflicts 15 to 20 percent of the United States population each year. Clinical Practice Guideline: Acute Low Back Problems in Adults (Confidential Review Draft) at 8 (attached at Exhibit 7 to Defendants' Reply Memorandum in Support of their Motion for Summary Judgment).

According to the draft CPG, back symptoms are "the most common cause of disability for persons under age 45." *Id.* (citation omitted). Complaints about lower back pain constitute the "second most common symptomatic reason expressed by patients for office visits to primary care physicians," the most common reason for office visits to orthopedic surgeons, neurosurgeons, and occupational medicine physicians, and the third most common reason for surgical procedures. *Id.* (citations omitted). Further, the loss of time as well as the disability payments for work-related back problems are said to cost up to three times as much as the medical treatment itself. *Id.* at 8-9. In sum, the annual societal cost of lower back pain is said to total as much as $50 billion. *Id.* at 9. With such a need for knowledge of the efficacy of different treatment options, Plaintiff has failed to demonstrate how the public would benefit from being denied access to the fruits of more than two years of research, review and study that have been spent compiling and examining the most recent medical knowledge regarding low back pain.

Accordingly, an injunction would be highly detrimental to the public interest, and its potential harms to the public would far outweigh the potential benefits to Plaintiff.

It is well established that injunctive relief is an "extraordinary remedy." *See, e.g., Weinberger v. Romero-*

Barcelo, 456 U.S. 305, 312 (1982). As explained above, such relief is not warranted in this case. Plaintiffs' Motion for Preliminary Injunction must be denied.

V. Conclusion

For the reasons stated above, Plaintiffs' Motions for Preliminary Injunction and for Summary Judgment shall be denied, and Defendants' Motion for Summary Judgment shall be granted.

An appropriate order follows.

DATE 12/6/94

/s/ Gladys Kessler
GLADYS KESSLER
United States District Judge

APPENDIX C

[Filed Dec. 6, 1994]

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

Civil Action No. 94-1120 (GK)

SOFAMOR DANEK GROUP, INC.,
Plaintiff,

v.

J. JARRETT CLINTON, *et. al.*,
Defendants.

ORDER

This matter is now before the Court upon Plaintiff's Motion for Preliminary Injunction, Defendants' Motion for Summary Judgment, and Plaintiffs' Motion for Summary Judgment.

For the reasons stated in the accompanying MEMORANDUM-OPINION, it is, this —— day of December, 1994, hereby

ORDERED, that Plaintiff's Motion for Preliminary Injunction is denied, and it is further

ORDERED, that Plaintiff's Motion for Summary Judgment is denied, and it is further

ORDERED, that Defendants' Motion for Summary Judgment is hereby granted in its entirety; and it is hereby

ORDERED, that Judgment shall be entered in favor of Defendants, and that Plaintiff's Complaint be dismissed in its entirety.

DATE 12/6/94

/s/ Gladys Kessler
GLADYS KESSLER
United States District Judge

APPENDIX D

[Filed Aug. 4, 1995]

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 94-5356

SOFAMOR DANEK GROUP, INCORPORATED,
Appellant

v.

CLIFTON R. GAUS, Administrator, AGENCY FOR HEALTH CARE POLICY and RESEARCH, DEPARTMENT OF HEALTH and HUMAN SERVICES, *et al.*,
Appellees

Appeal from the United States District Court
for the District of Columbia
(No. 94cv01120)

Before: EDWARDS, *Chief Judge*, ROGERS and TATEL, *Circuit Judges*.

JUDGMENT

This cause came on to be heard on the record on appeal from the United States District Court for the District of Columbia and was argued by counsel. On consideration thereof, it is

ORDERED and ADJUDGED, by the Court, that the judgment of the District Court appealed from in this cause is hereby affirmed, in accordance with the Opinion for the Court filed herein this date.

Per Curiam

FOR THE COURT

/s/ Mark J. Langer
MARK L. LANGER
Clerk

Date: August 4, 1995

Opinion for the Court filed by Circuit Judge Rogers.

APPENDIX E

FEDERAL ADVISORY COMMITTEE ACT

§ 1. Short title

This Act may be cited as the "Federal Advisory Committee Act".

§ 2. Findings and purpose

(a) The Congress finds that there are numerous committees, boards, commissions, councils, and similar groups which have been established to advise officers and agencies in the executive branch of the Federal Government and that they are frequently a useful and beneficial means of furnishing expert advice, ideas, and diverse opinions to the Federal Government.

(b) The Congress further finds and declares that—

(1) the need for many existing advisory committees has not been adequately reviewed;

(2) new advisory committees should be established only when they are determined to be essential and their number should be kept to the minimum necessary;

(3) advisory committees should be terminated when they are no longer carrying out the purposes for which they were established;

(4) standards and uniform procedures should govern the establishment, operation, administration, and duration of advisory committees;

(5) the Congress and the public should be kept informed with respect to the number, purpose, membership, activities, and cost of advisory committees; and

(6) the function of advisory committees should be advisory only, and that all matters under their consideration should be determined, in accordance with law, by the official, agency, or officer involved.

§ 3. Definitions

For the purpose of this Act—

(1) The term "Administrator" means the Administrator of General Services.

(2) The term "advisory committee" means any commitee, board, commission, council, conference, panel, task force, or other similar group, or any subcommittee or other subgroup thereof (hereafter in this paragraph referred to as "committee"), which is—

(A) established by statute or reorganization plan, or

(B) established or utilized by the President, or

(C) established or utilized by one or more agencies.

in the interest of obtaining advice or recommendation for the President or one or more agencies or officers of the Federal Government, except that such term excludes (i) the Advisory Commission on Intergovernmental Relations, (ii) the Commission on Government Procurement, and (iii) any committee which is composed wholly of full-time officers or employees of the Federal Government.

(3) The term "agency" has the same meaning as in section 551(1) of Title 5.

(4) The term "Presidential advisory committee" means an advisory committee which advises the President.

§ 4. Applicability; restrictions

(a) The provisions of this Act or of any rule, order, or regulation promulgated under this Act shall apply to each advisory committee except to the extent that any Act of Congress establishing any such advisory committee specifically provides otherwise.

(b) Nothing in this Act shall be construed to apply to any advisory committee established or utilized by—

(1) the Central Intelligence Agency; or

(2) the Federal Reserve System.

(c) Nothing in this Act shall be construed to apply to any local civic group whose primary function is that of rendering a public service with respect to a Federal program, or any State or local committee, council, board, commission, or similar group established to advise or make recommendations to State or local officials or agencies.

§ 5. Responsibilities of Congressional committees; review; guidelines

(a) In the exercise of its legislative review function, each standing committee of the Senate and the House of Representatives shall make a continuing review of the activities of each advisory committee under its jurisdiction to determine whether such advisory committee should be abolished or merged with any other advisory committee, whether the responsibilities of such advisory committee should be revised, and whether such advisory committee performs a necessary function not already being performed. Each such standing committee shall take appropriate action to obtain the enactment of legislation necessary to carry out the purpose of this subsection.

(b) In considering legislation establishing, or authorizing the establishment of any advisory committee, each standing committee of the Senate and of the House of

Representatives shall determine, and report such determination to the Senate or to the House of Representatives, as the case may be, whether the functions of the proposed advisory committee are being or could be performed by one or more agencies or by an advisory committee already in existence, or by enlarging the mandate of an existing advisory committee. Any such legislation shall—

(1) contain a clearly defined purpose for the advisory committee;

(2) require the membership of the advisory committee to be fairly balanced in terms of the points of view represented and the functions to be performed by the advisory committee;

(3) contain appropriate provisions to assure that the advice and recommendations of the advisory committee will not be inappropriately influenced by the appointing authority or by any special interest, but will instead be the result of the advisory committee's independent judgment;

(4) contain provisions dealing with authorization of appropriations, the date for submission of reports (if any), the duration of the advisory committee, and the publication of reports and other materials, to the extent that the standing committee determines the provisions of section 10 of this Act to be inadequate; and

(5) contain provisions which will assure that the advisory committee will have adequate staff (either supplied by an agency or employed by it), will be provided adequate quarters, and will have funds available to meet its other necessary expenses.

(c) To the extent they are applicable, the guidelines set out in subsection (b) of this section shall be followed by the President, agency heads, or other Federal officials in creating an advisory committee.

§ 6. Responsibilities of the President; report to Congress; annual report to Congress; exclusion

(a) The President may delegate responsibility for evaluating and taking action, where appropriate, with respect to all public recommendations made to him by Presidential advisory committees.

(b) Within one year after a Presidential advisory committee has submitted a public report to the President, the President or his delegate shall make a report to the Congress stating either his proposals for action or his reasons for inaction, with respect to the recommendations contained in the public report.

(c) The President shall, not later than December 31 of each year, make an annual report to the Congress on the activities, status, and changes in the composition of advisory committees in existence during the preceding fiscal year. The report shall contain the name of every advisory committee, the date of and authority for its creation, its termination date or the date it is to make a report, its functions, a reference to the reports it has submitted, a statement of whether it is an ad hoc or continuing body, the dates of its meetings, the names and occupations of its current members, and the total estimated annual cost to the United States to fund, service, supply, and maintain such committee. Such report shall include a list of those advisory committees abolished by the President, and in the case of advisory committees established by statute, a list of those advisory committees which the President recommends be abolished together with his reasons therefor. The President shall exclude from this report any information which, in his judgment, should be withheld for reasons of national security, and he shall include in such report a statement that such information is excluded.

§ 7. Responsibilities of the Administrator of General Services; Committee Management Secretariat, establishment; review; recommendations to President and Congress; agency cooperation; performance guidelines; uniform pay guidelines; travel expenses; expense recommendations

(a) The Administrator shall establish and maintain within the General Services Administration a Committee Management Secretariat, which shall be responsible for all matters relating to advisory committees.

(b) The Administrator shall, immediately after October 6, 1972, institute a comprehensive review of the activities and responsibilities of each advisory committee to determine—

(1) whether such committee is carrying out its purpose;

(2) whether, consistent with the provisions of applicable statutes, the responsibilities assigned to it should be revised;

(3) whether it should be merged with other advisory committees; or

(4) whether is should be abolished.

The Administrator may from time to time request such information as he deems necessary to carry out his functions under this subsection. Upon the completion of the Administrator's review he shall make recommendations to the President and to either the agency head or the Congress with respect to action he believes should be taken. Thereafter, the Administrator shall carry out a similar review annually. Agency heads shall cooperate with the Administrator in making the reviews required by this subsection.

(c) The Administrator shall prescribe administrative guidelines and management controls applicable to ad-

visory committees, and, to the maximum extent feasible, provide advice, assistance, and guidance to advisory committees to improve their performance. In carrying out his functions under this subsection, the Administrator shall consider the recommendations of each agency head with respect to means of improving the performance of advisory committees whose duties are related to such agency.

(d)(1) The Administrator after study and consultation with the Director of the Office of Personnel Management, shall establish guidelines with respect to uniform fair rates of pay for comparable services of members, staffs, and consultants of advisory committees in a manner which gives appropriate recognition to the responsibilities and qualifications required and other relevant factors. Such regulations shall provide that—

(A) no member of any advisory committee or of the staff of any advisory committee shall receive compensation at a rate in excess of the rate specified for GS-18 of the General Schedule under section 5332 of title 5, United States Code;

(B) such members, while engaged in the performance of their duties away from their homes or regular places of business, may be allowed travel expenses, including per diem in lieu of subsistence, as authorized by section 5703 of title 5, United States Code, for persons employed intermittently in the Government service; and

(C) such members—

(i) who are blind or deaf or who otherwise qualify as handicapped individuals (within the meaning of section 501 of the Rehabilitation Act of 1973 (29 U.S.C. 794)), and

(ii) who do not otherwise qualify for assistance under section 3102 of Title 5, by reason of being an employee of an agency (within the

meaning of section 3102(a)(1) of such Title 5),

may be provided services pursuant to section 3102 of such Title 5 while in performance of their advisory committee duties.

(2) Nothing in this subsection shall prevent—

(A) an individual who (without regard to his service with an advisory committee) is a full-time employee of the United States, or

(B) an individual who immediately before his service with an advisory committee was such an employee,

from receiving compensation at the rate at which he otherwise would be compensated (or was compensated) as a full-time employee of the United States.

(e) The Administrator shall include in budget recommendations a summary of the amounts he deems necessary for the expenses of advisory committees, including the expenses for publication of reports where appropriate.

§ 8. Responsibilities of agency heads; Advisory Committee Management Officer, designation

(a) Each agency head shall establish uniform administrative guidelines and management controls for advisory committees established by that agency, which shall be consistent with directives of the Administrator under section 7 and section 10. Each agency shall maintain systematic information on the nature, functions, and operations of each advisory committee within its jurisdiction.

(b) The head of each agency which has an advisory committee shall designate an Advisory Committee Management Officer who shall—

(1) exercise control and supervision over the establishment, procedures, and accomplishments of advisory committees established by that agency;

(2) assemble and maintain the reports, records, and other papers of any such committee during its existence; and

(3) carry out, on behalf of that agency, the provisions of section 552 of title 5. United States Code, with respect to such reports, records, and other papers.

§ 9. Establishment and purpose of advisory committees; publication in Federal Register; charter: filing, contents, copy

(a) No advisory committee shall be established unless such establishment is—

(1) specifically authorized by statute or by the President; or

(2) determined as a matter of formal record, by the head of the agency involved after consultation with the Administrator with timely notice pulished in the Federal Register, to be in the public interest in connection with the performance of duties imposed on that agency by law.

(b) Unless otherwise specifically provided by statute or Presidential directive, advisory committees shall be utilized solely for advisory functions. Determinations of action to be taken and policy to be expressed with respect to matters upon which an advisory committee reports or makes recommendations shall be made solely by the President or an officer of the Federal Government.

(c) No advisory committee shall meet or take any action until an advisory committee charter has been filed with (1) the Administrator, in the case of Presidential advisory committees, or (2) with the head of the agency

to whom any advisory committee reports and with the standing committees of the Senate and of the House of Representatives having legislative jurisdiction of such agency. Such charter shall contain the following information:

(A) the committee's official designation;

(B) the committee's objectives and the scope of its activity;

(C) the period of time necessary for the committee to carry out its purposes;

(D) the agency or official to whom the committee reports;

(E) the agency responsible for providing the necessary support for the committee;

(F) a description of the duties for which the committee is responsible, and, if such duties are not solely advisory, a specification of the authority for such functions;

(G) the estimated annual operating costs in dollars and man-years for such committee;

(H) the estimated number and frequency of committee meetings;

(I) the committee's termination date, if less than two years from the date of the committee's establishment; and

(J) the date the charter is filed.

A copy of any such charter shall also be furnished to the Library of Congress.

§ 10. Advisory committee procedures; meetings; notice, publication in Federal Register; regulations; minutes; certification; annual report; Federal officer or employee, attendance

(a)(1) Each advisory committee meeting shall be open to the public.

(2) Except when the President determines otherwise for reasons of national security, timely notice of each such meeting shall be published in the Federal Register, and the Administrator shall prescribe regulations to provide for other types of public notice to insure that all interested persons are notified of such meeting prior thereto.

(3) Interested persons shall be permitted to attend, appear before, or file statements with any advisory committee, subject to such reasonable rules or regulations as the Administrator may prescribe.

(b) Subject to section 552 of title 5. United States Code, the records, reports, transcripts, minutes, appendixes, working papers, drafts, studies, agenda, or other documents which were made available to or prepared for or by each advisory committee shall be available for public inspection and copying at a single location in the offices of the advisory committee or the agency to which the advisory committee reports until the advisory committee ceases to exist.

(c) Detailed minutes of each meeting of each advisory committee shall be kept and shall contain a record of the persons present, a complete and accurate description of matters discussed and conclusions reached, and copies of all reports received, issued, or approved by the advisory committee. The accuracy of all minutes shall be certified to by the chairman of the advisory committee.

(d) Subsections (a)(1) and (a)(3) of this section shall not apply to any portion of an advisory committee meeting where the President, or the head of the agency

to which the advisory committee reports, determines that such portion of such meeting may be closed to the public in accordance with subsection (c) of section 552b of title 5, United States Code. Any such determination shall be in writing and shall contain the reasons for such determination. If such a determination is made, the advisory committee shall issue a report at least annually setting forth a summary of its activities and such related matters as would be informative to the public consistent with the policy of section 552(b) of title 5, United States Code.

(e) There shall be designated an officer or employee of the Federal Government to chair or attend each meeting of each advisory committee. The officer or employee so designated is authorized, whenever he determines it to be in the public interest, to adjourn any such meeting. No advisory committee shall conduct any meeting in the absence of that officer or employee.

(f) Advisory committees shall not hold any meetings except at the call of, or with the advance approval of, a designated officer or employee of the Federal Government, and in the case of advisory committees (other than Presidential advisory committees), with an agenda approved by such officer or employee.

§ 11. Availability of transcripts; "agency proceeding"

(a) Except where prohibited by contractual agreements entered into prior to the effective date of this Act, agencies and advisory committees shall make available to any person, at actual cost of duplication, copies of transcripts of agency proceedings or advisory committee meetings.

(b) As used in this section "agency proceeding" means any proceeding as defined in section 551(12) of title 5, United States Code.

§12. Fiscal and administrative provisions; recordkeeping; audit; agency support services

(a) Each agency shall keep records as will fully disclose the disposition of any funds which may be at the disposal of its advisory committees and the nature and extent of their activities. The General Services Administration, or such other agency as the President may designate, shall maintain financial records with respect to Presidential advisory committees. The Comptroller General of the United States, or any of his authorized representatives, shall have access, for the purpose of audit and examination, to any such records.

(b) Each agency shall be responsible for providing support services for each advisory committee established by or reporting to it unless the establishing authority provides otherwise. Where any such advisory committee reports to more than one agency, only one agency shall be responsible for support services at any one time. In the case of Presidential advisory committees, such services may be provided by the General Services Administration.

§ 13. Responsibilities of Library of Congress; reports and background papers; depository

Subject to section 552 of title 5, United States Code, the Administrator shall provide for the filing with the Library of Congress of at least eight copies of each report made by every advisory committee and, where appropriate, background papers prepared by consultants. The Librarian of Congress shall establish a depository for such reports and papers where they shall be available to public inspection and use.

§ 14. Termination of advisory committees; renewal; continuation

(a)(1) Each advisory committee which is in existence on the effective date of this Act shall terminate not later

than the expiration of the two-year period following such effective date unless—

(A) in the case of an advisory committee established by the President or an officer of the Federal Government, such advisory committee is renewed by the President or that officer by appropriate action prior to the expiration of such two-year period; or

(B) in the case of an advisory committee established by an Act of Congress, its duration is otherwise provided for by law.

(2) Each advisory committee established after such effective date shall terminate not later than the expiration of the two-year period beginning on the date of its establishment unless—

(A) in the case of an advisory committee by the President or an officer of the Federal Government such advisory committee is renewed by the President or such officer by appropriate action prior to the end of such period; or

(B) in the case of an advisory committee established by an Act of Congress, its duration is otherwise provided for by law.

(b)(1) Upon the renewal of any advisory committee, such advisory committee shall file a charter in accordance with section 9(c).

(2) Any advisory committee established by an Act of Congress shall file a charter in accordance with such section upon the expiration of each successive two-year period following the date of enactment of the Act establishing such advisory committee.

(3) No advisory committee required under this subsection to file a charter shall take any action (other than preparation and filing of such charter) prior to the date on which such charter is filed.

(c) Any advisory committee which is renewed by the President or any officer of the Federal Government may be continued only for successive two-year periods by appropriate action taken by the President or such officer prior to the date on which such advisory committee would otherwise terminate.

§ 15. Effective date

Except as provided in section 7(b), this Act shall become effective upon the expiration of ninety days following October 6, 1972.

SUBCHAPTER VII—AGENCY FOR HEALTH CARE POLICY AND RESEARCH

PART A—ESTABLISHMENT AND GENERAL DUTIES

§ 299. Establishment

(a) In general

There is established within the Service an agency to be known as the Agency for Health Care Policy and Research.

(b) Purpose

The purpose of the Agency is to enhance the quality, appropriateness, and effectiveness of health care services, and access to such services, through the establishment of a broad base of scientific research and through the promotion of improvements in clinical practice (including the prevention of diseases and other health conditions) and in the organization, financing, and delivery of health care services.

(c) Appointment of Administrator

There shall be at the head of the Agency an official to be known as the Administrator for Health Care Policy and Research. The Administrator shall be appointed by the Secretary. The Secretary, acting through the Administrator, shall carry out the authorities and duties established in this subchapter.

§ 299a. General authorities and duties

(a) In general

In carrying out section 299(b) of this title, the Administrator shall conduct and support research, demonstration projects, evaluations, training, guideline development, and the dissemination of information, on health care services and on systems for the delivery of such services, including with respect to—

(1) the effectiveness, efficiency, and quality of health care services;

(2) subject to subsection (d) of this section, the outcomes of health care services and procedures;

(3) clinical practice, including primary care and practice-oriented research;

(4) health care technologies, facilities, and equipment;

(5) health care costs, productivity, and market forces;

(6) health promotion and disease prevention;

(7) health statistics and epidemiology; and

(8) medical liability.

(b) Requirements with respect to rural areas and underserved populations

In carrying out subsection (a) of this section, the Administrator shall undertake and support research, demonstration projects, and evaluations with respect to—

(1) the delivery of health care services in rural areas (including frontier areas); and

(2) the health of low-income groups, and the elderly.

(c) Health services training grants

The Administrator may provide training grants in the field of health services research related to activities authorized under subsection (a) of this section, to include pre- and post-doctoral fellowships and training programs, young investigator awards, and other programs and activities as appropriate.

(d) Multidisciplinary centers

The Administrator may provide financial assistance to public or nonprofit private entities for meeting the costs

of planning and establishing new centers, and operating existing and new centers, for multidisciplinary health services research, demonstration projects, evaluations, training, policy analysis, and demonstrations respecting the matters referred to in subsection (a) of this section.

(e) Relation to certain authorities regarding Social Security

Activities authorized in this section may include, and shall be appropriately coordinated with, experiments, demonstration projects, and other related activities authorized by the Social Security Act [42 U.S.C.A. § 301 et seq.] and the Social Security Amendments of 1967. Activities under subsection (a)(2) of this section that affect the programs under titles XVIII [42 U.S.C.A. § 1395 et seq.] and XIX [42 U.S.C.A. § 1396 et seq.] of the Social Security Act shall be carried out consistent with section 1142 of such Act [42 U.S.C.A. § 1320b-12].

§ 299a-1. Dissemination

(a) In general

The Administrator shall—

(1) promptly publish, make available, and otherwise disseminate, in a form understandable and on as broad a basis as practicable so as to maximize its use, the results of research, demonstration projects, and evaluations conducted or supported under this subchapter and the guidelines, standards, and review criteria developed under this subchapter;

(2) promptly make available to the public data developed in such research, demonstration projects, and evaluations;

(3) provide indexing, abstracting, translating, publishing, and other services leading to a more effective and timely dissemination of information on research, demonstration projects, and evaluations

with respect to health care to public and private entities and individuals engaged in the improvement of health care delivery and the general public, and undertake programs to develop new or improved methods for making such information available; and

(4) as appropriate, provide technical assistance to State and local government and health agencies and conduct liaison activities to such agencies to foster dissemination.

(b) Prohibition against restrictions

Except as provided in subsection (c) of this section, the Administrator may not restrict the publication or dissemination of data from, or the results of, projects conducted or supported under this subchapter.

(c) Limitation on use of certain information

No information, if an establishment or person supplying the information or described in it is identifiable, obtained in the course of activities undertaken or supported under this subchapter may be used for any purpose other than the purpose for which it was supplied unless such establishment or person has consented (as determined under regulations of the Secretary) to its use for such other purpose. Such information may not be published or released in other form if the person who supplied the information or who is described in it is identifiable unless such person has consented (as determined under regulations of the Secretary) to its publication or release in other form.

(d) Certain interagency agreement

The Administrator and the Director of the National Library of Medicine shall enter into an agreement providing for the implementation of subsection (a)(3) of this section.

(e) Required interagency agreement

The Administrator and the Director of the National Library of Medicine shall enter into an agreement providing for the implementation of section 286d of this title.

§ 299a-2. Health care technology and technology assessment

(a) In general

In carrying out section 299(b) of this title, the Administrator shall promote the development and application of appropriate health care technology assessments—

(1) by identifying needs in, and establishing priorities for, the assessment of specific health care technologies;

(2) by developing and evaluating criteria and methodologies for health care technology assessment;

(3) by conducting and supporting research on the development and diffusion of health care technology;

(4) by conducting and supporting research on assessment methodologies;

(5) by promoting education, training, and technical assistance in the use of health care technology assessment methodologies and results; and

(6) by conducting assessments and reassessments of existing and new health care technologies.

(b) Specific assessments

(1) In general

In carrying out section 299(b) of this title, the Administrator shall conduct and support specific assessments of health care technologies.

(2) Consideration of certain factors

In carrying out paragraph (1), the Administrator shall consider the safety, efficacy, and effectiveness, and, as appropriate, the legal, social, and ethical implications, and appropriate uses of such technologies, including consideration of geographic factors. In carrying out such paragraph, the Administrator shall also consider the cost effectiveness of such technologies where cost information is available and reliable.

(c) Agenda and priorities

(1) Establishment of priorities

In accordance with paragraph (2), the Administrator, in consultation with the Advisory Council established under section 299c of this title, shall establish an annual list of technology assessments under consideration by the Agency, including those assessments performed at the request of the Health Care Financing Administration and the Department of Defense and those assessments performed under subsections (d) and (f) of this section.

(2) Public notice

The Administrator, in consultation with the Advisory Council, shall publish the list established in paragraph (1) annually in the Federal Register.

(d) Conduct of assessments

(1) Recommendations with respect to health care technology

The Administrator shall make recommendations to the Secretary with respect to whether specific health care technologies should be reimbursable under federally financed health programs, including recommendations with respect to any conditions and requirements under which any such reimbursements should be made.

(2) Considerations of certain factors

In making recommendations respecting health care technologies, the Administrator shall consider the safety, efficacy, and effectiveness, and, as appropriate, the appropriate uses of such technologies. The Administrator shall also consider the cost effectiveness of such technologies where cost information is available and reliable.

(3) Additional assessments

The Administrator may conduct technology assessments in addition to those assessments performed at the request of the Administrator of the Health Care Financing Administration or of the Secretary of Defense.

(4) Criteria

The Administrator shall develop criteria for determining the priority of assessments performed under this subsection. Such criteria shall include—

(A) the prevalence of the health condition for which the technology aims to prevent, diagnose, treat and clinically manage;

(B) variations in current practice;

(C) the economic burden posed by the prevention, diagnosis, treatment, and clinical management of the health condition, including the impact on publicly-funded programs;

(D) aggregate cost of the use of technology;

(E) the morbidity and mortality associated with the health condition; and

(F) the potential of an assessment to improve health outcomes or affect costs associated with the prevention, diagnosis, or treatment of the condition.

(5) Consultations

In carrying out this subsection, the Administrator shall cooperate and consult with the Director of the National Institutes of Health, the Commissioner of Food and Drugs, and the heads of any other interested Federal department or agency.

(e) Description of process

Not later than January 1, 1994, the Administrator shall develop and publish a description of the methodology used to establish priorities for technology assessment and the process used to conduct its technology assessments under this section.

(f) Program of innovative assessments

(1) In general

The Administrator may make grants to, or enter cooperative agreements or contracts with, entities described in paragraph (2) for the establishment of collaborative arrangements for the purpose of conducting assessments of experimental, emerging, existing, or potentially outmoded health care technologies, and for related activities. Such assessments may include controlled clinical trials, large simple trials, and other methodologies that can be conducted in partnership between the public and private sectors or among multiple government agencies.

(2) Eligible entities

The entities referred to in paragraph (1) are entities determined to be appropriate by the Administrator, which entities may include academic medical centers, research institutions, nonprofit professional organizations, public or private third party payers, other governmental agencies, and consortia of appropriate research entities established for the purpose of conducting technology assessments.

(3) Use of award

A grant, cooperative agreement, or contract under paragraph (1) may be expended for data collection, data analysis, protocol development, report development, dissemination and evaluation, and other activities determined to be appropriate by the Administrator. Such funds shall not be used for direct services.

(4) Application for award

To be eligible to receive a grant, cooperative agreement, or contract under paragraph (1), an entity shall prepare and submit to the Administrator an application, at such time, in such form, and containing such information as the Administrator may require.

(5) Interagency memoranda of understanding

In carrying out paragraph (1), the Administrator may enter into memoranda of understanding with the heads of other Federal agencies.

PART B—FORUM FOR QUALITY AND EFFECTIVENESS IN HEALTH CARE

§ 299b. Establishment of office

There is established within the Agency an office to be known as the Office of the Forum for Quality and Effectiveness in Health Care. The office shall be headed by a director, who shall be appointed by the Administrator. The Administrator shall carry out this part acting through the Director.

§ 299b-1. Duties

(a) Establishment of forum program

The Administrator shall establish a program to be known as the Forum for Quality and Effectiveness

in Health Care. For the purpose of promoting the quality, appropriateness, and effectiveness of health care, the Administrator, using the process set forth in section 299b-2 of this title, shall arrange for the development and periodic review and updating of—

(1) clinically relevant guidelines that may be used by physicians, educators, and health care practitioners to assist in determining how diseases, disorders, and other health conditions can most effectively and appropriately be prevented, diagnosed, treated, and managed clinically; and

(2) standards of quality, performance measures, and medical review criteria through which health care providers and other appropriate entities may assess or review the provision of health care and assure the quality of such care.

(b) Certain requirements

Guidelines, standards, performance measures, and review criteria under subsection (a) of this section shall—

(1) be based on the best available research and professional judgment regarding the effectiveness and appropriateness of health care services and procedures;

(2) be presented in formats appropriate for use by physicians, health care practitioners, providers, medical educators, and medical review organizations and in formats appropriate for use by consumers of health care;

(3) include treatment-specific or condition-specific practice guidelines for clinical treatments and conditions in forms appropriate for use in clinical practice, for use in educational programs, and for use in reviewing quality and appropriateness of medical care; and

(4) include information on risks and benefits of alternative strategies for prevention, diagnosis, treatment, and management of a given disease, disorder, or other health condition; and

(5) include information on the costs of alternative strategies for the prevention, diagnosis, treatment, and management of a given disease, disorder, or other health condition, where cost information is available and reliable.

(c) Authority for contracts

In carrying out this part, the Administrator may enter into contracts with public or nonprofit private entities.

(d) Date certain for initial guidelines and standards

The Administrator, by not later than January 1, 1991, shall assure the development of an initial set of guidelines, standards, performance measures, and review criteria under subsection (a) of this section that includes not less than 3 clinical treatments or conditions described in section 1142(a)(3) of the Social Security Act [42 U.S.CA. § 1320b-12(a)(3)].

(e) Relationship with Medicare program

To assure an appropriate reflection of the needs and priorities of the program under title XVIII of the Social Security Act [42 U.S.C.A. § 1395 et seq.], activities under this part that affect such program shall be conducted consistent with section 1142 of such Act [42 U.S.C.A. § 1320b-12].

(f) Development of certain guidelines and standards

Not later than January 1, 1996, the Administrator shall ensure that a set of guidelines, standards, performance measures, and review criteria, are developed under subsection (a)(1) of this section that address the prevention of not fewer than three conditions that account for sig-

nificant national health expenditures. In carrying out this subsection the Administrator shall consult with the United States Preventive Services Task Force and other recognized experts in the field of disease prevention.

§ 299b-2. Process for development of guidelines and standards

(a) Development through contracts and panels

The Administrator shall—

(1) enter into contracts with public and nonprofit entities for the purpose of developing and periodically reviewing and updating the guidelines, standards, performance measures, and review criteria described in section 299b-1(a) of this title; and

(2) convene panels of appropriately qualified experts (including practicing physicians with appropriate expertise) and health care consumers for the purpose of—

(A) developing and periodically reviewing and updating the guidelines, standards, performance measures, and review criteria described in section 299b-1(a) of this title; and

(B) reviewing the guidelines, standards, performance measures, and review criteria developed under contracts under paragraph (1).

(b) Authority for additional panels

The Administrator may convene panels of appropriately qualified experts (including practicing physicians with appropriate expertise) and health care consumers for the purpose of—

(1) developing the standards and criteria described in section 299b-3(b) of this title; and

(2) providing advice to the Administrator and the Director with respect to any other activities carried out under this part or under section 299a(a)(2) of this title.

(c) Selection of panel members

The Administrator shall select the chairpersons and the members of the panels convened as well as other participants in the guideline process under this section. In selecting individuals to serve on panels convened under this section, the Administrator shall consult with a broad range of interested individuals and organizations, including organizations representing physicians in the general practice of medicine and organizations representing physicians in specialties and subspecialties pertinent to the purposes of the panel involved. The Administrator shall seek to appoint physicians reflecting a variety of practice settings. In making such selections, the Administrator shall ensure that a balance is maintained between individuals selected from academic settings and individuals selected without full-time academic appointments. At least two other members of such panels shall be individuals who do not derive their primary source of revenue directly from the performance of procedures discussed in the guideline. The Administrator shall ensure that at least one participant in the guideline process shall have expertise in epidemiology as well as familiarity with the clinical condition of treatment in question. The Administrator shall also ensure that at least one participant in the guideline process shall have expertise in health services research or health economics as well as familiarity with the clinical condition or treatment in question.

§ 299b-3. Additional requirements

(a) Program agenda

(1) In general

The Administrator shall provide for an agenda for the development of the guidelines, standards, performance measures, and review criteria described in section 299b-1(a) of this title, including—

(A) with respect to the guidelines, identifying specific diseases, disorders, and other health conditions for which the guidelines are to be developed and those that are to be given priority in the development of the guidelines; and

(B) with respect to the standards, performance measures, and review criteria, identifying specific aspects of health care for which the standards, performance measures, and review criteria are to be developed and those that are to be given priority in the development of the standards, performance measures, and review criteria.

(2) Consideration of certain factors in establishing priorities

(A) Factors considered by the Administrator in establishing priorities for purposes of paragraph (1) shall include consideration of the extent to which the guidelines, standards, performance measures, and review criteria involved can be expected—

(i) to improve methods for disease prevention;

(ii) to improve methods of diagnosis, treatment, and clinical management for the benefit of a significant number of individuals; and

(iii) to reduce clinically significant variations among physicians in the particular ser-

vices and procedures utilized in making diagnoses and providing treatments; and

(iv) to reduce clinically significant variations in the outcomes of health care services and procedures.

(B) In providing for the agenda required in paragraph (1), including the priorities, the Administrator shall consult with the Administrator of the Health Care Financing Administration and otherwise act consistent with section 1320b-12(b)(3) of this title.

(C) The Administrator shall develop and publish a methodology for establishing priorities for guideline topics. Such methodology may include the considerations described in section 299a-2(d)(2) of this title or subsection (a)(2) of this section, and other considerations determined by the Administrator to be appropriate. Using such methodology, the Administrator shall establish and publish annually in the Federal Register a list of guideline topics under consideration.

(b) Standards and criteria

(1) Process for development, review, and updating

The Administrator shall establish standards and criteria to be utilized by the recipients of contracts under section 299b-2 of this title, and by the expert panels convened under such section, with respect to the development and periodic review and updating of the guidelines, standards, performance measures, and review criteria described in section 299b-1(a) of this title.

(2) Award of contracts

The Administrator shall establish standards and criteria to be utilized for the purpose of ensuring

that contracts entered into for the development or periodic review or updating of the guidelines, standards, performance measures, and review criteria described in section 299b-1(a) of this title will be entered into only with appropriately qualified entities.

(3) Certain requirements for standards and criteria

The Administrator shall ensure that the standards and criteria established under paragraphs (1) and (2) specify that—

(A) appropriate consultations with interested individuals and organizations are to be conducted in the development of the guidelines, standards, performance measures, and review criteria described in section 299b-1(a) of this title: and

(B) such development may be accomplished through the adoption, with or without modification, of guidelines, standards, performance measures, and review criteria that—

(i) meet the requirements of this part; and

ii) are developed by entities independently of the program established in this part.

(4) Improvements of standards and criteria

The Administrator shall conduct and support research with respect to improving the standards and criteria developed under this subsection.

(c) Dissemination

The Administrator shall promote and support the dissemination of the guidelines, standards, performance measures, and review criteria described in section 299b-1(a)

of this title. Such dissemination shall be carried out through organizations representing health care providers, organizations representing health care consumers, peer review organizations, accrediting bodies, and other appropriate entities.

(d) Pilot testing

The Administrator may conduct or support pilot testing of the guidelines, standards, performance measures, and review criteria developed under section 299b-1(a) of this title. Any such pilot testing may be conducted prior to, or concurrently with, their dissemination under subsection (c) of this section.

(e) Evaluations

The Administrator shall conduct and support evaluations of the extent to which the guidelines, standards, performance standards, and review criteria developed under section 299b-1 of this title have had an effect on the clinical practice of medicine. Evaluations shall be developed prior to the completion and release of the guideline, so that baseline data concerning practice patterns and health care costs may be obtained as part of the evaluation.

(f) Recommendations to Administrator

The Director shall make recommendations to the Administrator on activities that should be carried out under section 299a(a)(2) of this title and under section 1320-b-12 of this title, including recommendations of particular research projects that should be carried out with respect to—

(1) evaluating the outcomes of health care services and procedures;

(2)developing the standards and criteria required in subsection (b) of this section; and

(3) promoting the utilization of the guidelines, standards, performance standards, and review criteria developed under section 299b-1(a) of this title.

PART C—GENERAL PROVISIONS

§ 299c. Advisory Council for Health Care Policy, Research, and Evaluation

(a) Establishment

There is established an advisory council to be known as the National Advisory Council for Health Care Policy, Research, and Evaluation.

(b) Duties

(1) In general

The Council shall advise the Secretary and the Administrator with respect to activities to carry out the purpose of the Agency under section 299(b) of this title.

(2) Certain recommendations

Activities of the Council under paragraph (1) shall include making recommendations to the Administrator regarding priorities for a national agenda and strategy for—

(A) the conduct of research, demonstration projects, and evaluations with respect to health care, including clinical practice and primary care;

(B) the development and application of appropriate health care technology assessments;

(C) the development and periodic review and updating of guidelines for clinical practice, standards of quality, performance measures, and

medical review criteria with respect to health care; and

(D) the conduct of research on outcomes of health care services and procedures.

(c) Membership

(1) In general

The Council shall, in accordance with this subsection, be composed of appointed members and ex officio members. All members of the Council shall be voting members, other than officials designated under paragraph (3)(B) as ex officio members of the Council.

(2) Appointed members

The Secretary shall appoint to the Council 17 appropriately qualified representatives of the public who are not officers or employees of the United States. The Secretary shall ensure that the appointed members of the Council, as a group, are representatives of professions and entities concerned with, or affected by, activities under this subchapter and under section 1320b-12 of this title. Of such members—

(A) 8 shall be individuals distinguished in the conduct of research, demonstration projects, and evaluations with respect to health care;

(B) 3 shall be individuals distinguished in the practice of medicine;

(C) 2 shall be individuals distinguished in the health professions;

(D) 2 shall be individuals distinguished in the fields of business, law, ethics, economics, and public policy; and

(E) 2 shall be individuals representing the interests of consumers of health care.

(3) Ex officio members

The Secretary shall designate as ex officio members of the Council—

(A) the Director of the National Institutes of Health, the Director of the Centers for Disease Control, the Administrator of the Health Care Financing Administration, the Assistant Secretary of Defense (Health Affairs), the chief Medical Officer of the Department of Veterans Affairs; and

(B) such other Federal officials as the Secretary may consider appropriate.

(d) Terms

(1) In general

Except as provided in paragraph (2), members of the Council appointed under subsection (c)(2) of this section shall serve for a term of 3 years.

(2) Staggered rotation

Of the members first appointed to the Council under subsection (c)(2) of this section, the Secretary shall appoint 6 members to serve for a term of 3 years, 6 members to serve for a term of 2 years, and 5 members to serve for a term of 1 year.

(3) Service beyond term

A member of the Council appointed under subsection (c)(2) of this section may continue to serve after the expiration of the term of the member until a successor is appointed.

(e) Vacancies

If a member of the Council appointed under subsection (c)(2) of this section does not serve the full term applicable under subsection (d) of this section, the in-

dividual appointed to fill the resulting vacancy shall be appointed for the remainder of the term of the predecessor of the individual.

(f) Chair

The Administrator shall, from among the members of the Council appointed under subsection (c)(2) of this section, designate an individual to serve as the chair of the Council.

(g) Meetings

The Council shall meet not less than once during each discrete 4-month period and shall otherwise meet at the call of the Administrator or the chair.

(h) Compensation and reimbursement of expenses

(1) Appointed members

Members of the Council appointed under subsection (c)(2) of this section shall receive compensation for each day (including traveltime) engaged in carrying out the duties of the Council. Such compensation may not be in an amount in excess of the maximum rate of basic pay payable for GS-18 of the General Schedule.

(2) Ex officio members

Officials designated under subsection (c)(3) of this section as ex officio members of the Council may not receive compensation for service on the Council in addition to the compensation otherwise received for duties carried out as officers of the United States.

(i) Staff

The Administrator shall provide to the Council such staff, information, and other assistance as may be necessary to carry out the duties of the Council.

(j) Duration

Notwithstanding section 14(a) of the Federal Advisory Committee Act, the Council shall continue in existence until otherwise provided by law.

(k) Redesignated (j)

§ 299c-1. Peer review with respect to grants and contracts

(a) Requirement of review

(1) In general

Appropriate technical and scientific peer review shall be conducted with respect to each application for a grant, cooperative agreement, or contract under this subchapter.

(2) Reports to Administrator

Each peer review group to which an application is submitted pursuant to paragraph (1) shall report its finding and recommendations respecting the application to the Administrator in such form and in such manner as the Administrator shall require.

(b) Approval as precondition of awards

The Administrator may not approve an application described in subsection (a)(1) of this section unless the application is recommended for approval by a peer review group established under subsection (c) of this section.

(c) Establishment of peer review groups

(1) In general

The Administrator shall establish such technical and scientific peer review groups as may be necessary to carry out this section. Such groups shall be

established without regard to the provisions of Title 5 that govern appointments in the competitive service, and without regard to the provisions of chapter 51, and subchapter III of chapter 53, of such title that relate to classification and pay rates under the General Schedule.

(2) Membership

The members of any peer review group established under this section shall be appointed from among individuals who by virtue of their training or experience are eminently qualified to carry out the duties of such peer review group. Officers and employees of the United States may not constitute more than 25 percent of the membership of any such group. Such officers and employees may not receive compensation for service on such groups in addition to the compensation otherwise received for duties carried out as such officers and employees.

(3) Duration

Notwithstanding section 14(a) of the Federal Advisory Committee Act, peer review groups established under this section shall continue in existence until otherwise provided by law.

(d) Categories of review

(1) In general

With respect to technical and scientific peer review under this section, there shall be two categories of peer review groups as follows:

(A) One category of such groups shall, subject to subparagraph (B), review applications with respect to research, demonstration projects, or evaluations.

(B) The other category of such groups shall review applications with respect to dissemina-

tion activities or the development of research agendas (including conferences, workshops, and meetings). If the purpose of a proposal presented in an application is a matter described in the preceding sentence, the application shall be reviewed by the groups referred to in such sentence, notwithstanding that the proposal involves research, demonstration projects, or evaluations.

(2) Authority for procedural adjustments in certain cases

In the case of applications described in subsection (a)(1) of this section for financial assistance whose direct costs will not exceed $50,000, the Administrator may make appropriate adjustments in the procedures otherwise established by the Administrator for the conduct of peer review under this section. Such adjustments may be made for the purpose of encouraging the entry of individuals into the field of research, for the purpose of encouraging clinical practice-oriented research, and for such other purposes as the Administrator may determine to be appropriate.

(e) Regulations

The Secretary shall issue regulations for the conduct of peer review under this section.

§ 299c-2. Certain provisions with respect to development, collection, and dissemination of data

(a) Standards with respect to utility of data

(1) In general

With respect to data developed or collected by any entity for the purpose described in section 299(b) of this title (the Administrator shall, in order to as-

sure the utility, accuracy, and sufficiency of such data for all interested entities, establish guidelines for uniform methods of developing and collecting such data. Such guidelines shall include specifications for the development and collection of data on the outcomes of health care services and procedures.

(2) Relationship with Medicare program

In any case where guidelines under paragraph (1) may affect the administration of the program under title XVIII of the Social Security Act [42 U.S.C.A. § 1395 et seq.], the guidelines shall be in the form of recommendations to the Secretary for such program.

(b) Statistics

The Administrator shall—

(1) take such action as may be necessary to assure that statistics developed under this subchapter are of high quality, timely, and comprehensive, as well as specific, standardized, and adequately analyzed and indexed; and

(2) publish, make available, and disseminate such statistics on as wide a basis as is practicable.

(c) Authority regarding certain requests

Upon the request of a public or nonprofit private entity, the Administrator may tabulate and analyze statistics under arrangements under which such entity will pay the cost of the service provided. Amounts appropriated to the Administrator from payments made under such arrangements shall be available to the Administrator for obligation until expended.

§ 299c-3. Additional provisions with respect to grants and contracts

(a) Financial conflicts of interest

With respect to projects for which awards of grants, cooperative agreements, or contracts are authorized to be made under this subchapter, the Administrator shall by regulation define—

(1) the specific circumstances that constitute financial interests in such projects that will, or may be reasonably expected to, create a bias in favor of obtaining results in the projects that are consistent with such interests; and

(2) the actions that will be taken by the Administrator in response to any such interests identified by the Administrator.

(b) Requirement of application

The Administrator may not, with respect to any program under this subchapter authorizing the provision of grants, cooperative agreements, or contracts, provide any such financial assistance unless an application for the assistance is submitted to the Secretary and the application is in such form, is made in such manner, and contains such agreements, assurances, and information as the Administrator determines to be necessary to carry out the program involved.

(c) Provision of supplies and services in lieu of funds

(1) In general

Upon the request of an entity receiving a grant, cooperative agreement, or contract under this subchapter, the Secretary may, subject to paragraph (2), provide supplies, equipment, and services for the purpose of aiding the entity in carrying out the project involved and, for such purpose, may detail to the

entity any officer or employee of the Department of Health and Human Services.

(2) Corresponding reduction in funds

With respect to a request described in paragraph (1), the Secretary shall reduce the amount of the financial assistance involved by an amount equal to the costs of detailing personnel and the fair market value of any supplies, equipment, or services provided by the Administrator. The Secretary shall, for the payment of expenses incurred in complying with such request, expend the amounts withheld.

(d) Applicability of certain provisions with respect to contracts

Contracts may be entered into under this part without regard to sections 3324(a) and (b) of Title 31 and section 5 of Title 41.

§ 299c-5. Funding

(a) Authorization of appropriations

For the purpose of carrying out this subchapter, there are authorized to be appropriated $115,000,000 for fiscal year 1993, $145,000,000 for fiscal year 1994, and $175,000,000 for fiscal year 1995.

(b) Evaluations

In addition to amounts available pursuant to subsection (a) of this section for carrying out this subchapter, there shall be made available for such purpose, from the amounts made available pursuant to section 238j of this title (relating to evaluations), an amount equal to 40 percent of the maximum amount authorized in such section 238j of this title to be made available.

(c) Information center

For purposes of carrying out the activities under section 299a-1(e) of this title, there are authorized to be appropriated $3,000,000 for fiscal year 1993, and such sums as may be necessary for each of the fiscal years 1994 and 1995.

(d) Health care technology assessment

For the purpose of carrying out technology assessment activities under section 299a-2(d) of this title, there are authorized to be appropriated $2,000,000 for fiscal year 1993, and such sums as may be necessary for each of the fiscal years 1994 and 1995.

(e) Program of innovative assessments

For purposes of establishing the program of innovative assessments under section 299a-2(f) of this title, there are authorized to be appropriated $2,000,000 for fiscal year 1993, and such sums as may be necessary in each of the fiscal years 1994 and 1995.